UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA *ex rel.* [SEALED], and on behalf of the STATES of CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, WASHINGTON, the COMMONWEALTH OF MASSACHUSETTS, the COMMONWEALTH OF VIRGINIA, the COMMONWEALTH OF PUERTO RICO, the DISTRICT OF COLUMBIA, the CITY OF CHICAGO, the CITY OF HALLANDALE BEACH, BROWARD COUNTY, MIAMI-DADE COUNTY, the PEOPLE OF CALIFORNIA, and the PEOPLE OF ILLINOIS,

Plaintiff-Relator,

vs.

[SEALED]

Collectively, "Defendant."

Case Number:

Jury Trial Demanded

COMPLAINT FOR VIOLATIONS OF THE FALSE CLAIMS ACT, STATE LAW COUNTERPARTS, LOCAL LAW COUNTERPARTS, THE CALIFORNIA INSURANCE FRAUD PREVENTION ACT, AND THE ILLINOIS INSURANCE CLAIMS FRAUD PREVENTION ACT

FILED UNDER SEAL

DO NOT PLACE ON PACER

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA *ex rel.* VRAYLAR LITIGATION PARTNERSHIP, LLP, and on behalf of the STATES of CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, freNEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, WASHINGTON, the COMMONWEALTH OF MASSACHUSETTS, the COMMONWEALTH OF VIRGINIA, the COMMONWEALTH OF PUERTO RICO, the DISTRICT OF COLUMBIA, the CITY OF CHICAGO, the CITY OF HALLANDALE BEACH, BROWARD COUNTY, MIAMI-DADE COUNTY, the PEOPLE OF CALIFORNIA, and the PEOPLE OF ILLINOIS, Plaintiff-Relator, vs. ALLERGAN, PLC, ALLERGAN USA, INC., ALLERGAN FINANCE, LLC. Collectively, "Defendant."	Case Number: **Jury Trial Demanded** **COMPLAINT FOR VIOLATIONS OF THE FALSE CLAIMS ACT, STATE LAW COUNTERPARTS, LOCAL LAW COUNTERPARTS, THE CALIFORNIA INSURANCE FRAUD PREVENTION ACT, AND THE ILLINOIS INSURANCE CLAIMS FRAUD PREVENTION ACT** ***FILED UNDER SEAL*** ***DO NOT PLACE ON PACER***

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COMPLAINT FOR FALSE CLAIMS ACT VIOLATIONS UNDER 31 U.S.C. § 3729 *ET SEQ.*, STATE LAW, AND LOCAL LAW COUNTERPARTS

1. This action is brought on behalf of the United States of America and the following states and localities by the Vraylar Litigation Partnership LLP ("Relator"), by and through its attorneys, against Defendants Allergan plc, Allergan USA, Inc., and Allergan Finance, LLC ("Defendant" or "Allergan") pursuant to the *qui tam* provisions of the Federal Civil False Claims Act, 31 U.S.C. § 3729 *et seq.*("FCA"); the California False Claims Act, Cal. Gov't Code §§ 12650 *et seq.*; the Colorado Medicaid False Claims Act, Colo. Rev. Stat. §§ 25.5-4-304 *et seq.*; the Connecticut False Claims Act, Conn. Gen. Stat. tit. 4 Ch. 55e §§ 4-274 *et seq.*; the Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, §§ 1201 *et seq.*; the District of Columbia False Claims Act, D.C. Code §§ 2-308.13 *et seq.*; the Florida False Claims Act, Fla. Stat. tit. 6, §§ 68.081 *et seq.*; the Georgia False Medicaid Claims Act, Ga. Code Ann. §§ 49-4-168 *et seq.*; the Hawaii False Claims Act, Haw. Rev. Stat. §§ 661-21 *et seq.*; the Illinois False Claims Act, 740 Ill. Comp. Stat. §§ 175/1 *et seq.*; the Indiana Medicaid False Claims and Whistleblower Protection Act, Ind. Code §§ 5-11-5.7 *et seq.*; the Iowa False Claims Act, Iowa Code §§ 685.1 *et seq.*; the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. §§ 46:437.1 *et seq.*; the Maryland False Health Claims Act, Md. Code Ann., Health-Gen. §§ 2-601 *et seq.*; the Massachusetts False Claims Act, Mass. Gen. Laws ch. 12, §§ 5A *et seq.*; the Michigan Medicaid False Claims Act, Mich. Comp. Laws §§ 400.601 *et seq.*; the Minnesota False Claims Act, Minn. Stat. §§ 15C.01 *et seq.*; the Montana False Claims Act, Mont. Code Ann. §§ 17-8-401 *et seq.*; the Nevada False Claims Act, Nev. Rev. Stat. §§ 357.010 *et seq.*; the New Jersey False Claims Act, N.J. Stat. Ann. §§ 2A:32C-1 *et seq.*; the New Mexico Fraud Against Taxpayers Act, N.M. Stat. Ann. §§ 44-9-3(C)(1) *et seq.*; the New York False Claims Act, N.Y. State Fin. Law Art. XIII §§ 187 *et seq.*; the

North Carolina False Claims Act, N.C. Gen. Stat. §§ 1-605 *et seq.*; the Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63, §§ 5053 *et seq.*; the Rhode Island False Claims Act, R.I. Gen. Laws §§ 9-1.1-1 *et seq.*; the Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§ 71-5-181 *et seq.*; the Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code Ann. §§ 36.001 *et seq.*; the Texas Medical Assistance Program, Damages, and Penalties Act, Tex. Hum. Res. Code. Ann. §§ 32.039 *et seq.*; the Vermont False Claims Act, Vt. Stat. Ann. tit. 32 §§ 631 *et seq.*; the Virginia Fraud Against Taxpayers Act, Va. Code Ann. §§ 8.01-216.1 *et seq.*; the Washington State Medicaid False Claims Act, Wash. Rev. Code. §§ 74.66.005 *et seq.*; and the False Claims to Government of Puerto Rico Programs, Contracts, and Services Act, 2018 P.R. Act 154 (H.B. 1627) (the aforementioned statutes referred to collectively as the "state Whistleblower Statutes" and the collection of states as "Whistleblower States" or "*Qui Tam* States"); pursuant to the Chicago False Claims Ordinance, Chicago Mun. Code §§ 1-21-010 to -060, the City of Hallandale Beach False Claims Ordinance, Hallandale Beach Code of Ordinances §§ 8-201 to -210, the Broward County False Claims Ordinance, Broward Cnty. Code of Ordinances §§ 1-276 to -287, and the Miami-Dade County False Claims Ordinance, Miami-Dade Cty. Code §§ 21-255 to -266 (the aforementioned ordinances referred to collectively as the "Locality Whistleblower Ordinances" and the collection of localities as "Whistleblower Localities"); and pursuant to the California Insurance Fraud Prevention Act, Cal. Ins. Code § 1871.7 ("CIFPA"), and the Illinois Insurance Claims Fraud Prevention Act, 740 Ill. Comp. Stat. §§ 92/1 *et seq*. ("IICFPA").

I. INTRODUCTION

2. In September 2015, Allergan received Food and Drug Administration ("FDA") approval for Vraylar, a second generation atypical antipsychotic, for the treatment of Schizophrenia and the acute treatment of mixed or manic episodes associated with Bipolar I

Disorder. In the over four years since its launch, Vraylar has become a blockbuster drug, earning Allergan $487 million in 2018 and increasing that amount by a whopping 76% in 2019 with total sales of $857.5 million. This Complaint alleges that such large sales numbers are due largely to Allergan's illegal, off-label promotional and kickback scheme for Vraylar.

3. While Allergan has paid lip service to its compliance obligations by purging off-label content from official promotional materials, slide decks, and national sales meetings, and even included admonitions against off-label promotion, during district sales meetings Allergan managers have regularly continued to insist that sales representatives promote Vraylar by making what it knew were illegal, false, and materially misleading claims to health care professionals. The reality of Allergan's off-label promotion therefore has been concealed behind a veneer of compliance—a veneer that Allergan hoped would hide its fraud by instructing sales representatives not to discuss off-label promotion in e-mail, voicemail, or call notes—all the while aggressively promoting the drug for off-label uses.

4. The off-label uses for which Allergan promoted Vraylar included treatment of unipolar depression, including Major Depressive Disorder ("MDD"); generalized symptoms not consistent with its indicated uses; and a litany of off-label child and adolescent uses, including treatment of behavioral symptoms. Vraylar has not been demonstrated to be safe and effective for any of these uses. In fact, for every one of these uses, clinical trials have either failed to demonstrate an efficacy benefit, or have found that the safety risks accompanying use of the drug were too great to justify whatever efficacy was observed.

5. In order to convince health care professionals to prescribe Vraylar for these off-label uses, Allergan has regularly concealed and distorted evidence concerning not only the efficacy, but also the safety, of the drug. Vraylar is an atypical antipsychotic and its use is

accompanied by risk of serious adverse events including Akathisia, hyperglycemia and diabetes, hyperlipidemia, dyslipidemia, and weight gain.

6. For the FDA approved uses of Vraylar, assumption of these risks is frequently warranted by the accompanying efficacy benefit. The assumption of Vraylar's significant safety risks, however, was not warranted for the off-label uses for which Allergan has promoted the drug, either because Vraylar did not effectively treat those uses, or because those uses were more effectively treated by safer and much cheaper alternatives. By misleading health care professionals regarding Vraylar's true safety and efficacy profiles, Allergan exposed patients to unnecessary risk of serious medical harm.

7. Allergan has tried to exploit that Vraylar's indicated use – Bipolar Depression – appears to have similar symptoms to unipolar depression or MDD. In reality, however, Bipolar Depression and MDD are very different conditions and cannot be conflated. The seriousness of the conditions is different (Bipolar Depression is far more serious and difficult to treat). The treatments for each condition are different (different medications are used for each condition). These are all facts Allergan knows well because the FDA specifically rejected Vraylar's application for an indication to treat depression because of a lack of efficacy data and the risk of serious side effects.

8. Yet, Allergan has been more motivated to tap into the far more lucrative market for treating MDD than it was concerned that exposing patients to the risks of using its powerful atypical antipsychotic drug, even though it knew there was little substantial clinical evidence patients would receive any benefit and would instead face potentially serious adverse events from its use.

9. Given the significant differences in the disease states and risks associated with Vraylar, using it to treat MDD is like dropping an atom bomb to kill a fly. Allergan did not care. Instead, it directed its sales representatives to market Vraylar (including by providing copious quantities of free samples) to prescribers who it knew would not use the drug on-label (*e.g.*, primary care physicians, child and adolescent psychiatrists, and neurologists), even though the patients they treat would not use the drug on-label.

10. Allergan also violated Federal and State laws and regulations when it provided illegal kickbacks to health care professionals to induce them to prescribe (or to reward them for continuing to prescribe) Vraylar. This misconduct put patients at risk and it cheated Government Programs out of hundreds of millions of dollars in claims tainted by illegal kickbacks.

11. Even worse, despite knowing the serious risks associated with Vraylar, Allergan instructed its sales representatives not to report adverse events associated with Vraylar use. This abhorrent conduct meant that Allergan concealed the scale of reported negative (sometimes even fatal) outcomes from using its powerful drug off-label.

12. This conduct has persisted despite very troubling reports of serious adverse events. Even though Allergan sales representatives were directed not to report adverse events experienced with the drug, the past eight (8) months since Vraylar gained the additional indication for Bipolar Depression have seen a very disturbing fifteen (15) deaths reported.[1] This is in stark contrast to the period of nearly four (4) years starting from Vraylar's initial launch which saw "only" eleven (11) deaths reported as adverse events associated with Vraylar.

[1] FDA Adverse Event Reporting System (FAERS), *available at*: https://fis.fda.gov/sense/app/d10be6bb-494e-4cd2-82e4-0135608ddc13/sheet/33a0f68e-845c-48e2-bc81-8141c6aaf772/state/analysis (last visited February 24, 2020).

13. As a result of Allergan's rampant off-label promotion, health care professionals have written, and Government Programs have in turn reimbursed, many thousands prescriptions of Vraylar for off-label uses and/or which were tainted by kickbacks that were ineligible for reimbursement under Government Programs. As such, these claims were false and fraudulent, and Allergan is liable under the federal False Claims Act, and state law and local law counterparts for causing their submission.

14. Allergan's conduct has had a material effect on the Government Programs' decisions to pay for Vraylar. Had the Government Programs known that false Vraylar claims for had been submitted as the result of Allergan's illegal off-label promotion and kickback scheme, including an alarming record of serious adverse events and deaths, they would not have made those reimbursements.

15. This conduct is ongoing.

II. JURISDICTION AND VENUE

16. The Court has subject-matter jurisdiction over this action pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. § 1345. The Court has personal jurisdiction over the Defendants because, among other things, the Defendants sold Vraylar and engaged in wrongdoing in this district.

17. Venue is proper in this district under 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1391(b) and (c). Acts proscribed by 31 U.S.C. § 3729 occurred in this district.

18. The claims for relief alleged herein are timely brought because, among other things, the Defendants sought to conceal from the United States, the state governments, and local government their wrongdoing in connection with the allegations made herein.

III. PARTIES

A. Relator Vraylar Litigation Partnership, LLP

19. Relator Vraylar Litigation Partnership, LLP (hereinafter "Relator"), a Delaware limited liability partnership, brings this action on behalf of itself, the United States of America, the Whistleblower States, the Whistleblower Localities, and the People of California and Illinois. The registered office of Relator is located at 1925 Lovering Avenue, Wilmington, Delaware 19806, and the name of the registered agent at such address is The First State Registered Agent Company.

20. Pursuant to Section 15-201(a) of the Delaware Revised Uniform Partnership Act, Relator is not distinct from its partners, who, by virtue of employment with Allergan, at all times material hereto have had firsthand, personal knowledge of the false claims, statements, and concealments alleged herein.

21. At least one of the Relator's partners was employed by Allergan from 2018 to present. This partner has extensive personal knowledge and experience regarding Allergan's fraudulent scheme described in this Complaint, including personal contact with the employees and executives who have committed violations of law alleged herein.

22. Relator and its partners thus have direct knowledge of the conduct alleged in this Complaint and conducted an independent investigation to uncover false claims submitted to the United States, Whistleblower states, and Whistleblower localities. Accordingly, Relator is an "original source" of the non-public information alleged in this Complaint within the meaning of the federal FCA, state false claims acts, and locality false claims acts.

B. Defendants Allergan plc., Allergan USA, Inc., and Allergan Finance, LLC

23. Defendant Allergan plc (f/k/a Actavis plc, f/k/a Allergan, Inc.) is one of the world's largest pharmaceutical companies and is a foreign entity headquartered in Dublin, Ireland.

24. Allergan plc operates a "U.S. Administrative Headquarters" located at 5 Giralda Farms, Madison, New Jersey 07940.

25. Defendant Allergan USA, Inc. is a Delaware corporation with its headquarters located at 5 Giralda Farms, Madison, New Jersey 07940. Allergan USA, Inc. is a wholly-owned subsidiary of Allergan plc.

26. Defendant Allergan Finance, LLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.) is a Nevada Corporation with its headquarters located at 5 Giralda Farms Madison, NJ 07940.

27. Actavis plc acquired Forest Laboratories, Inc. on July 1, 2014 in a cash and equity transaction valued at approximately $28 billion.

28. On March 17, 2015, Actavis plc acquired Allergan, Inc. for $70 billion, and in the process completed a corporate tax inversion.

29. In June 2015, Actavis plc took the Allergan plc name for the combined group. At the time of the corporate tax inversion to Ireland, over 85% of the combined sales of the post-merger Allergan plc were from the U.S. healthcare system, and Irish sales were too small to be categorized.

30. Despite the corporate tax inversion, Allergan plc never left New Jersey because, as its CEO stated at the time "[e]verybody loves New Jersey too much, so nobody is willing to go."[2]

31. Allergan plc maintains a substantial presence and has maintained continuous, systematic, and substantial contacts with New Jersey and the United States, including in this

[2] Sloan, Allan, *When U.S. firms decide to 'desert' the country, we all pay a price*, Washington Post (November 4, 2015), https://www.washingtonpost.com/business/economy/when-us-firms-decide-to-desert-the-country-we-all-pay-a-price/2015/11/04/83c18714-831e-11e5-9afb-0c971f713d0c_story.html

judicial district. Allergan plc and its subsidiaries marketed and sold substantial quantities of its drug products in New Jersey and the United States, including in this Judicial District. Allergan plc not only benefited from the acts of its wholly owned affiliates and subsidiaries, but was directly involved in the False Claims Act violations alleged herein.

32. Allergan plc and its U.S. subsidiaries all maintain their principal places of business in the United States at the same location in Madison, New Jersey.

33. Allergan plc and its U.S. subsidiaries function as one, integrated entity. Allergan plc's U.S. subsidiaries have no independent decision-making capabilities and all facets of their operations are dominated, controlled and directed by Allergan plc.

34. Seven of Allergan plc's eight executive officers also serve as the top officers of Allergan Finance, LLC.

35. As a result of the control exerted by Allergan plc, all financial gains and losses by Allergan plc's U.S. subsidiaries inure directly to the benefit or detriment of Allergan plc and its shareholders.

36. Internet searches for Allergan USA, Inc., Allergan Finance, LLC, Forest Laboratories, Actavis plc, and Forest Laboratories, Inc., invariably lead to the Allergan plc website.

37. Although most of the financial information included in Allergan plc's 2018 Annual Report is presented in consolidated fashion, the report breaks out U.S. sales for Vraylar. 100% of worldwide sales of Vraylar are generated in the United States.

38. During the relevant time period, Allergan plc designed, produced, marketed and promoted mental health prescription medications, including Vraylar, nationwide. At all relevant times, Allergan plc acted by and through its agents, servants, workers, employees, officers

and directors, all acting through the course and scope of their actual and apparent authority, agency, duties or employment.

39. Throughout the relevant period, Allergan plc marketed and sold substantial quantities of its drug products (including Vraylar) in this district and throughout the rest of the United States. Defendant Allergan plc benefited from and is liable for the actions of its predecessors, affiliates and subsidiaries in carrying out the fraudulent scheme described below. Allergan plc has had notice of these fraudulent acts due to the substantial continuity in ownership and management with its subsidiary corporations and partnerships.

40. On June 25, 2019, AbbVie Inc. and Allergan plc announced that the companies had entered into a definitive transaction agreement under which AbbVie will acquire Allergan plc in a cash and stock transaction for a transaction equity value of approximately $63 billion, based on the closing price of AbbVie's common stock of $78.45 on June 24, 2019. The transaction is expected to close in early 2020, subject to customary closing conditions and regulatory approvals.

41. Defendants market and sell brand-name prescription drug products (including Vraylar) that are paid for or reimbursed by various governmental programs, including health benefit carriers offering benefits under the Federal Employees Health Benefits ("FEHB") program; the Health Insurance Program for the Elderly and Disabled, more commonly referred to as the Medicare Program, 42 U.S.C. § 1395, *et seq.*, via Medicare Part C, also known as Medicare+ Choice; Medicare Part D; the Indian Health Service; Medicaid; the Mail Handler's Health Benefit Plan ("MHHBP"); the U.S. Secret Service Employees Health Association ("SSEH") Health Benefit Plan; the Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS," now known as "TRICARE"); the Veteran's Health Administration ("VHA"), and various State employee, child, and prisoner health care programs (collectively, the "Government Programs").

42. As a result of Allergan's actions, the Government Programs have suffered financial harm.

43. The conduct alleged herein is ongoing.

IV. BACKGROUND OF THE REGULATORY FRAMEWORK

A. The FDA Regulatory System

1. The FDA Regulates What Drugs May Be Marketed, and the Uses For Which They May Be Marketed

44. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301-97, new drugs cannot be marketed in the United States unless the sponsor of the drug demonstrates to the satisfaction of the FDA that the drug is safe and effective for each of its intended uses.[3] Approval of the drug by the FDA is the final step in a multi-year process of study and testing.

45. To determine whether a drug is "safe and effective," the FDA relies on information provided by a drug's manufacturer; it does not conduct any substantial analysis or studies itself. Applications for FDA approval (known as New Drug Applications or "NDAs") must include "full reports of investigations which have been made to show whether or not such drug is safe for use and whether or not such drug is effective in use."[4]

46. Under the FDCA, a drug may not be introduced into interstate commerce unless its sponsor has shown that the drug is safe and effective for the intended conditions of use. [5] The law requires that "adequate and well-controlled investigations" be used to demonstrate a drug's safety and effectiveness.[6] The FDA approves a drug if there are "adequate and well-controlled clinical

[3] 21 U.S.C. § 355(a), (d).
[4] 21 U.S.C. § 355(b)(1)(A).
[5] *See* 21 U.S.C. § 321.
[6] 21 U.S.C. § 355(d)(7).

trials" that demonstrate a drug's safety and effectiveness for its "intended conditions" of use.[7] The "intended conditions" for use of a drug are listed in the drug's labeling, which is reviewed and approved by the FDA.[8] Indications for use that are not listed in a drug's labeling have not been approved by the FDA.[9]

47. The law requires that "adequate and well-controlled investigations" be used to demonstrate a drug's safety and effectiveness.[10] The FDA approves a drug if there are "adequate and well-controlled clinical trials" that demonstrate a drug's safety and effectiveness for its "intended conditions" of use.[11]

48. The standards that govern the FDA safety and effectiveness requirements are contained in statutes, regulations, notices and guidance documents. The statutory requirement that a drug's effectiveness be demonstrated by "adequate and well-controlled clinical investigations" has been interpreted to mean a clinical study with: (1) clear objectives; (2) adequate design to permit a valid comparison with a control group; (3) adequate selection of study subjects; (4) adequate measures to minimize bias; and (5) well defined and reliable methods of assessing subjects' responses to treatment.[12]

49. After a drug is approved, the FDA continues to exercise control over the product labeling. To ensure or promote safety, the FDA may require a label change to reflect the increased risk of various side effects or interactions, restrict a drug's indications, or, in extreme cases, force a withdrawal from the market.[13]

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[7] 21 U.S.C. § 355(d)(5).
[8] 21 U.S.C. § 355(d)(1) & (2).
[9] 37 Fed. Reg. 16,503 (1972).
[10] *See* 21 U.S.C. § 355(d)(7).
[11] *See* 21 U.S.C. § 355(d)(5).
[12] *See* 21 C.F.R. § 314.126.
[13] *See* 21 C.F.R. § 201.57(3).

50. The FDA determines the requirements for package inserts or prescribing information that is provided with a prescription medication, which provides information about that drug. The FDA may require that the package insert contain a "black box" warning. A black box warning means that medical studies indicate that the drug carries a significant risk of serious or even life-threatening adverse effects.

2. FDA Regulations Prohibit False and Misleading Claims about a Drug's Use

51. FDA regulations restrict how drug companies may market and promote approved drugs.[14] Drug labels – including all marketing and promotional materials relating to the drug – may not describe intended uses for the drug that have not been approved by the FDA.[15] Illegal "misbranding" can result in criminal penalties.[16]

52. The same general requirements governing the promotion of prescription drugs apply to both professional and consumer-oriented marketing. In particular, promotional materials may only make claims that are supported by "substantial" scientific evidence (according to strict scientific procedures) and they may not be false or misleading. FDA oversight helps ensure a "fair balance" in all promotional claims and materials. Federal regulations require that the risks as well as the benefits be clearly identified and given appropriate prominence. Promotional materials must be consistent with the FDA-approved product labeling. This restriction pertains to the clinical indications for which the drug has been approved as well as the dosing regimen that is supported by the clinical trials that were undertaken to establish safety and efficacy.

[14] *See* 21 U.S.C. §§ 331, 352; 21 C.F.R. § 314.81.
[15] 21 U.S.C. §§ 331, 352.
[16] *See* 21 U.S.C. § 333.

53. A manufacturer wishing to market or otherwise promote an approved drug for uses other than those listed on the approved label must resubmit the drug for a series of clinical trials similar to those required for the initial FDA approval.[17] A supplemental NDA ("sNDA") must be filed in order to seek approval of the new indication. Unless and until an additional indication is approved by the FDA, the unapproved use is considered to be "off-label."

54. "Off-label" refers to the use of an approved drug for any purpose, or in any manner, other than what is described in the drug's labeling. Off-label uses include treating a condition not indicated on the label, treating the indicated condition at a different dose or frequency than specified on the label, or treating a different patient population – *e.g.,* treating a child when the drug is only approved to treat adults.

55. Although the FDA is responsible for ensuring that a drug is safe and effective for the specific approved indication, the FDA does not regulate the practice of medicine. Once a drug is approved for a particular use, the FDA does not prohibit physicians from prescribing the drug for uses that are different than those approved by the FDA.

56. When considering whether to prescribe a drug, health care professionals depend on the patient-specific evidence available to them. This includes the particular patient's symptoms and medical history, the severity of his or her problems, the success of prior treatment, and the risks of not treating. Whether contemplating FDA-approved or unapproved uses, health care professionals also rely on personal experience, recommendations from colleagues and academics, educational seminars, and clinical trials evidence. Much of what health care professionals rely on

[17] *See* Food and Drug Administration Modernization Act of 1997 ("FDMA"), 21 U.S.C. §§ 360aaa(b), (c); *see also* 21 C.F.R. § 314.54 (outlining the administrative procedure for filing an application for a new indication); 21 U.S.C. §§ 301 *et seq.*

is information (or, as the case may be, misinformation) provided by sales representatives from drug makers.

57. Many healthcare providers rely on pharmaceutical sales representatives to assist in their prescribing decisions and many health care professionals place a deep sense of trust in their sales representatives. This trust can influence the medications they prescribe, including off-label prescribing due to misinformation from the sales representatives who are paid commissions based on increasing sales volume with prescribers.

58. Although health care professionals may prescribe drugs for unapproved usages, the law prohibits drug manufacturers from marketing or promoting a drug for a use that the FDA has not approved, or for a patient group that is unapproved. Specifically, a manufacturer illegally "misbrands" a drug if the drug's labeling (which includes all marketing and promotional materials relating to the drug) describes intended uses for the drug that have not been approved by the FDA.[18] The statute, 21 U.S.C. § 331(d), and its implementing regulations, and 21 C.F.R. § 202.1(e)(4)(i)(a), prohibit any advertising that recommends or suggests an off-label use for an approved drug.

59. The FDA has interpreted "advertising" to include a significant amount of speech that would not typically be considered advertising.[19] The FDA "interprets the term 'advertisement' to include information (other than labeling) that originates from the same source as the product and that is intended to supplement or explain the product."[20]

[18] 21 U.S.C. §§ 331, 352.
[19] *See* Final Guidance on Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. 64,074, 64,076 (Dec. 3, 1997).
[20] *Id.*

60. Any manufacturer oral or written information explaining one of its products is an "advertisement" for the product and is subject to the prohibitions against unsafe and ineffective marketing contained in 21 C.F.R. § 202.1, as well as the FDA's "fair balance" requirement, described below.

61. FDA regulations provide that an advertisement may not use "literature, quotations, or references for the purpose of recommending or suggesting conditions of drug use that are not approved or permitted in the drug package labeling."[21]

62. These regulations ban advertisements that are false, lacking in fair balance, or otherwise misleading. Thus, the use of unsubstantiated comparative claims also is prohibited by law.[22]

63. The regulations also prohibit an advertisement that "contains a representation or suggestion that a drug is safer than it has been demonstrated to be by substantial evidence or substantial clinical experience, by selective presentation of information from published articles or other references that report no side effects or minimal side effects with the drug or otherwise selects information from any source in a way that makes a drug appear to be safer than has been demonstrated."[23]

64. The regulations require drug companies to present a "true statement" of information relating to the side effects, contraindications and effectiveness of the drug use.[24] A company violates this regulation if it presents "false or misleading" information about a drug's

[21] 21 C.F.R. § 202.1(e)(6)(xi); *see also* 21 U.S.C. § 331(d) (prohibiting distribution of a drug for non-approved uses); *id.* § 331(a) (prohibiting distribution of a misbranded drug); *id.* § 360aaa (permitting dissemination of material on off-label uses only if the manufacturer meets certain stringent requirements).
[22] *See* 21 U.S.C. § 352; 21 C.F.R. § 202.1(e)(6).
[23] *See* 21 C.F.R. § 202.1(e)(6)(iv).
[24] *See* 21 C.F.R. § 202.1(e)(5) *et seq*.

side effects or does not "fair[ly] balance" information relating to the safety and efficacy of the drug use against information about its side effects and contraindications.[25]

65. FDA regulations broadly describe "labeling" of a drug as including any material accompanying a drug product that is supplied and disseminated by the manufacturer, packer or distributor of the drug.[26] The FDA has interpreted oral communications as falling under the umbrella of "labeling."

66. FDA regulations require labeling to be "informative and accurate and neither promotional in tone nor false and misleading in any particular," to "contain a summary of the essential scientific information needed for the safe and effective use of the drug," and prohibit "implied claims or suggestions of drug use if there is inadequate evidence of safety or a lack of substantial evidence of effectiveness."[27]

67. These regulations also lay out the stringent requirements that must be met by a manufacturer before it may disseminate any materials on unapproved or new uses of marketed drugs. This material must be in the form of an unabridged reprint or copy of a published, peer-reviewed article that is considered "scientifically sound" by experts qualified to evaluate the safety or effectiveness of the drug involved.[28] The FDA does not consider abstracts of publications to be "scientifically sound."[29] Unabridged reprints or copies of articles shall not be disseminated with any information that is promotional in nature.[30]

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[25] *Id.*
[26] 21 C.F.R. § 202.1(1)(2).
[27] 21 C.F.R. § 201.56.
[28] *See* 21 C.F.R. § 99.101(a)(2).
[29] *Id.* § 99.101(b).
[30] *Id.* § 99.101(b)(2).

68. Furthermore, the manufacturer must not disseminate materials that are "false and misleading," such as those that only present favorable information when unfavorable publications exist, exclude mandatory information about the safety and efficacy of the drug use, or present conclusions that "clearly cannot be supported by the results of the study."[31]

69. Information about unapproved uses may be disseminated only in response to an "unsolicited request from a healthcare practitioner."[32] In any other circumstance, a manufacturer may disseminate information concerning unapproved uses only after the manufacturer has submitted an application to the FDA seeking approval of the drug for the unapproved use; has provided the materials to the FDA prior to dissemination; and the materials themselves are submitted in unabridged form and are neither false nor misleading.[33]

70. Companies such as Allergan may not promote their approved drugs through unsubstantiated comparative claims that exalt their drugs as safer as or more efficacious than competitor drugs. Such promotion renders a drug "misbranded" and no longer eligible for reimbursement by Government Programs.

71. In sum, the regulatory regime protects patients and consumers by ensuring that drug companies do not promote drugs for uses other than those found to be safe and effective by an independent, scientific government body—the FDA. Moreover, the prohibition on claims regarding promoting drugs for unapproved uses protects patients and consumers by ensuring that the prescription and use of approved drugs is not based on a drug maker's misleading marketing tactics.

[31] 21 C.F.R. § 99.101(a)(4).
[32] 21 U.S.C. § 360aaa-6.
[33] 21 U.S.C. §§ 360aaa(b) & (c); 360aaa-1.

B. The FDA Relies on Information Provided by Drug Manufacturers for New Drug Approvals

72. FDA approval of prescription drugs is wholly dependent on the accuracy of information provided by drug manufacturers.[34]

73. FDA approval does not require that a new drug be more effective or safer than other drugs approved to treat the same condition, or that the new drug is more cost effective. A drug need only be shown to be more effective than a placebo in treating a particular condition, without any statistically significant safety findings. Comparative data showing performance as compared to existing drugs is not required; the FDA has no basis for determining that one drug is better than another drug.

74. Because short-term studies are accepted, FDA drug applications often do not contain long-term data on the safety or efficacy of the drug. Approval of a new drug generally contains a requirement that the manufacturers pursue further long-term studies, but two-thirds of the promised studies never materialize and the FDA lacks any enforcement authority to require the manufacturer to complete these studies.

75. Many of the effects of newly approved drugs could not possibly be known at the time of FDA approval, particularly the long-term effects of taking a medication, given the short length of and relatively few participants in the clinical trials conducted for approval.[35] There is no systematic provision requiring drug companies to conduct—or provide results from—post-marketing studies.

[34] *See generally* Wayne A. Ray & Michael Stein, "Reform of Drug Regulation—Beyond an Independent Drug-Safety Board," 354 *New England Journal of Medicine* 194 (Jan. 12, 2006).
[35] *See* "AP Analysis: How a Drug's Risks Emerge," *New York Times*, May 23, 2007.

76. The FDA often finds itself in a quandary: "Safety and speed are the yin and yang of drug regulation. Patients want immediate access to breakthrough medicines but also want to believe the drugs are safe. These goals can be incompatible."[36]

77. Once a drug has been approved, the FDA's statutory authority is limited to requesting label changes, negotiating with the manufacturer restrictions on distribution, and petitioning for the withdrawal of the drug from the marketplace. Title 21 of the Code of Federal Regulations requires that "as soon as there is reasonable evidence of a serious hazard with a drug," the "Warnings" section of the label should be revised to reflect this hazard.[37]

C. The Anti-Kickback Statute

78. The federal health care Anti-Kickback Statute, 42 U.S.C. §1320a-7b(b) ("AKS"), arose out of Congressional concern that payoffs to those who can influence health care decisions will result in goods and services being provided that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect the integrity of federal health care programs from these difficult to detect harms, Congress enacted a prohibition against the payment of kickbacks in any form, regardless of whether the particular kickback actually gives rise to overutilization or poor quality of care.

79. The AKS prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending, or arranging for the purchase of any item for which payment may be made under a federally-funded health care program.[38] Under this statute, drug companies may not offer or pay any remuneration, in cash or kind, directly or

[36] Gardiner Harris, "Potentially Incompatible Goals at F.D.A.: Critics Say a Push to Approve Drugs Is Compromising Safety," *New York Times*, June 11, 2007, at A14.
[37] 21 C.F.R. § 201.80(e).
[38] 42 U.S.C. § 1320a-7b(b).

indirectly, to induce health care professionals or others to order or recommend drugs that may be paid for by a federal health care program. The law not only prohibits outright bribes and rebate schemes, but also prohibits any payment by a drug company in cash or in kind that has as one of its purposes inducement of a physician to write additional prescriptions for the company's pharmaceutical products.

80. Violation of the AKS subjects the violator to exclusion from participation in federal health care programs, civil monetary penalties, and imprisonment of up to five years per violation.[39]

81. Concern about improper drug marketing practices like those alleged in this Complaint prompted the Inspector General of the Department of Health and Human Services ("HHS") to issue a Special Fraud Alert in 1994 identifying prescription drug marketing practices that violate the AKS.[40]

82. Among the suspect practices cited by the Inspector General were payments or gifts to health care professionals who had offered no particular services of benefit to the drug company, but who had generated in the past, or had the potential to generate in the future, a large volume of business for the drug company.[41]

83. In May 2003, the Inspector General of HHS released a further Guidance identifying in greater detail several marketing practices of drug manufacturers that constitute "kickbacks and other illegal remuneration" infecting federal health care programs.[42] The 2003 Guidance cautions manufacturers that any time a manufacturer provides anything of value to a physician who might

[39] 42 U.S.C. §§ 1320a-7(b)(7), 1320a-7a(a)(7).
[40] Special Fraud Alert: Prescription Drug Marketing Schemes, 59 Fed. Reg. 65,376 (Dec. 19, 1994).
[41] *Id.*
[42] OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731 (May 5, 2003).

prescribe the manufacturer's product(s), the manufacturer should examine whether it is providing a valuable tangible benefit to the physician with the intent to induce or reward referrals.

84. The OIG Guidance lists the following, among others, as suspect practices: (a) Improper Switching Arrangements: These are arrangements by which pharmaceutical manufacturers offer health care professionals cash or other benefits to change prescriptions from a competitor's product to the manufacturer's product. (b) Improper Consulting and Advisory Payments: These are payments made pursuant to less than bona fide consulting or advisory arrangements, such as payments to health care professionals for simply attending meetings or conferences in a passive capacity, or for services connected with a manufacturer's marketing activities. (c) Improper Payments for Detailing: These are payments to health care professionals for time spent listening to sales representatives' market pharmaceutical products, or for accessing web sites to view marketing information. (d) Improper Business Courtesies and Other Gratuities: These are gifts such as merchandise of more than trivial value, entertainment, recreation, travel, meals, and other gratuities furnished in association with information or marketing presentations. (e) Improper Educational and Research Funding: This refers to funding for research or education that is initiated or influenced by the manufacturers' sales or marketing departments.[43]

85. Compliance with the AKS is a precondition to participation as a health care provider under the Medicaid, CHAMPUS/TRICARE, CHAMPVA, the Federal Employee Health Benefit Program, and other federal health care programs. With regard to Medicaid, for example, each physician and pharmacist that participates in the program must sign a provider agreement with his or her state. Although there are variations in the agreements among the states, the

[43] *Id.* at 23731-39.

agreement typically requires the prospective Medicaid provider to agree that he or she will comply with all Medicaid requirements, which include the anti-kickback provisions of the law. In a number of other states, the Medicaid claim form itself contains a certification by the provider that the provider has complied with all aspects of the Medicaid program, including compliance with Federal laws.

86. In sum, either pursuant to provider agreements, claims forms, or other appropriate manner, health care professionals who participate in a federal health care program generally must certify that they have complied with the applicable federal rules and regulations, including the AKS.

87. Any party convicted under the AKS must be excluded (*i.e.,* not allowed to bill for services rendered) from federal health care programs for a term of at least five years.[44] Even without a conviction, if the Secretary of HHS finds administratively that a provider has violated the statute, the Secretary may exclude that provider from the federal health care programs for a discretionary period (in which event the Secretary must direct the relevant State agency(ies) to exclude that provider from the State health program), and may consider imposing administrative sanctions of $50,000 per kickback violation.[45]

88. The enactment of these various provisions and amendments demonstrates Congress' commitment to the fundamental principle that federal health care programs will not tolerate the payment of kickbacks. Thus, compliance with the AKS is a prerequisite to a provider's right to receive or retain reimbursement payments from Medicaid and other federal health care programs. Reimbursement is also prohibited by the general legal principle that providers who are

[44] 42 U.S.C. §1320a-7(a)(1).
[45] 42 U.S.C. § 1320a-7(b).

corrupt or unethical or violate the integrity of a government program involving government funds are not entitled to payment from the public for the resulting claims.

V. PRESCRIPTION DRUG PAYMENT UNDER GOVERNMENT HEALTH CARE PROGRAMS

89. Whether a drug is FDA approved for a particular indication (*i.e.*, use) and whether that indication is recommended in one or more of the statutorily named drug Compendia determines whether a prescription for that use may be reimbursed under Medicaid and other federal health care programs.

A. The Medicaid Program

90. Medicaid is a public assistance program providing for payment of medical expenses for approximately 75 million low-income patients. Funding for Medicaid is shared between the federal and state governments. Prior to the advent of Medicare Part D in 2006, the Medicaid program subsidized the purchase of more prescription drugs than any other program in the United States.

91. Although Medicaid is administered on a state-by-state basis, the state programs adhere to federal guidelines. Federal statutes and regulations restrict the drugs and drug uses that the Federal Government will pay for through its funding of state Medicaid programs. Federal reimbursement for prescription drugs under the Medicaid program is limited to "covered outpatient drugs."[46] Covered outpatient drugs are drugs that are used for "a medically accepted indication."[47]

92. A medically-accepted indication, in turn, is a use that is listed in the labeling approved by the FDA, or that is included in one of the drug Compendia identified in the Medicaid

[46] 42 U.S.C. §§ 1396b(I)(10), 1396r-8(k)(2)-(3).
[47] 42 U.S.C. § 1396r-8(k)(3).

statute.[48] The three statutorily named Compendia are the American Hospital Service Formulary Drug Information ("AHFS"), United States Pharmacopeia-Drug Information or its successor publications ("USP-DI"), and the DRUGDEX Information System ("Drugdex").[49]

B. The Medicare Program

93. Medicare is a public health care program that provides coverage for Americans over the age of 65, as well as other persons with certain disabilities and diseases.

94. Starting in January 2006, Part D of the Medicare Program provided subsidized drug coverage for all Medicare beneficiaries, with low-income individuals receiving the greatest subsidies.[50]

95. Medicare Part D covers pharmacy-dispensed outpatient drugs. Part D also requires that a "covered Part D drug" be used for a "medically accepted indication (as defined in paragraph (4)."[51] Paragraph 4 in turn refers to the Medicaid definition of medically accepted indication under 42 U.S.C. § 1396r8 (k)(6), which specifies that medically accepted uses are those "supported by one or more citations included or approved for inclusion in" AHFS, Drugdex, or USP-DI. Thus, in order to be reimbursable by Medicare Part D, the off-label use of a drug must be supported by one or more of AHFS, Drugdex, or USP-DI.

96. Part D requires beneficiaries to enroll and pay certain premiums, deductibles, copayments, and even 100% of drug costs between a certain dollar threshold and a maximum dollar limit (the "donut hole"), that then triggers catastrophic coverage. The federal government pays 75% of actual costs between the deductible and the donut hole, and 95% of catastrophic

[48] 42 U.S.C. § 1396r-8(k)(6).
[49] *See* 42 U.S.C. § 1396r-8(g)(1)(B)(i).
[50] 42 U.S.C. § 1395w-101 *et seq*.
[51] 42 U.S.C. § 1395w–102(e)(1).

coverage. For low-income individuals, there are various tiers in which the government pays greater percentages, up to a 100% subsidy which may be capitated.

97. Health care providers can only submit claims to Medicare if they are a registered and authorized Medicare provider. To obtain that status, a health care provider must execute a Medicare Provider Application and Provider Agreement. These documents set forth language through which the provider expressly undertakes to comply with all conditions of payment, including compliance with all relevant laws and guidance defining the limits of coverage. These documents do not obligate the health care professional to provide any goods or services to beneficiaries, and hence are part of a unilateral contract between the provider and the government. As a unilateral contract, acceptance is evidenced by performance in the form of delivering services or goods to a beneficiary, for which the provider then submits a claim for payment to the government. In other words, the claim implicitly represents legal entitlement to payment.

98. Medicare Part D pricing is based on a quasi-free market model. At the end of the day, however, it is still a per-item payment system.

99. Medicare contracts with private Part D providers (also known as "sponsors" or "contractors") to administer prescription drug plans.

100. A sponsor must submit a bid in the year prior to the calendar year in which Part D benefits will be delivered.[52] The bid contains a per member per month (PMPM) cost estimate for providing Part D benefits to an average Medicare beneficiary in a particular geographic area. From these bids, CMS calculates nationwide and regional benchmarks which represent the average

[52] *See* 42 C.F.R § 423.265.

PMPM cost. If the Part D sponsor's bid exceeds the benchmark, the enrolled beneficiary must pay the difference as part of the monthly beneficiary premium.

101. CMS provides each sponsor with a direct subsidy in the form of advance monthly payments equal to the Part D plan's standardized bid, risk adjusted for health status, minus the monthly beneficiary premium, estimated reinsurance subsidies for catastrophic coverage, and estimated low-income subsidies.[53]

102. In the year following the benefit year, there is a reconciliation based on the actual claims paid for the Part D sponsor's member beneficiaries, and an adjustment is made so that Medicare Part D is ultimately only paying for the drugs actually dispensed.

103. Of key importance here, sponsors must certify in their contracts with CMS their agreement to comply with all federal laws and regulations designed to prevent fraud, waste, and abuse.[54] In turn, the sponsor's contracts with downstream entities, including pharmacies and Pharmacy Benefit Managers ("PBMs"), must contain similar language obligating those entities to comply with all applicable federal laws, regulations, and CMS instructions when submitting Part D claims data or otherwise acting as the sponsor's agent.[55]

104. When a pharmacy dispenses drugs to a Medicare beneficiary, it submits a claim electronically to the beneficiary's Part D plan (usually via the sponsor's contracted PBM) and receives reimbursement from the plan sponsor for the portion of the drug cost not paid by the beneficiary.

[53] 42 C.F.R. §§ 423.315, 423.329.
[54] 42 C.F.R. § 423.505(h)(1).
[55] 42 C.F.R. § 423.505(i)(4)(iv).

105. The sponsor (again usually through its contracted PBM) then notifies CMS that a drug has been purchased and dispensed by means of a document called a Prescription Drug Event record ("PDE"), which is an electronically created document that includes 37 fields of information including the amount paid to the pharmacy. Submission to CMS of truthful and accurate PDEs for each prescription is a condition of payment.

106. In the year following the benefit year, CMS uses a sponsor's PDEs to compare the sponsor's actual prescription drug costs to CMS's advance payments to the sponsor. If a sponsor's actual costs exceed the sums it received from CMS for the year, the plan sponsor recoups its losses from CMS. Conversely, if a sponsor's actual costs were less than the sums it received from CMS for the year, CMS recoups the overpayments by reducing subsequent payments to the sponsor. These reconciliation payments are subject to application of certain statutorily defined risk-sharing corridors.

107. Sponsors subcontract with many entities to provide drugs to the Medicare Part D beneficiaries enrolled in their plans. These include subcontracts with PBMs that provide drugs through mail order operations and pharmacy chains which provide drugs on a retail level.

C. TRICARE

108. In addition to Medicare and Medicaid, Allergan caused submission of false claims to other government-funded healthcare programs. One program was the DoD's healthcare system, TRICARE, formerly known as the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), which provides care for approximately eight million people. TRICARE provides healthcare to active duty service personnel and to non-active duty beneficiaries, including dependents of active duty personnel and military retirees and their dependents.

109. TRICARE operates through military hospitals and clinics worldwide and is supplemented through contracts with civilian healthcare providers. TRICARE is a triple-option benefit program designed to give beneficiaries a choice among health maintenance organizations, preferred provider organizations, and fee-for-service benefits. Five managed-care contractors create networks of civilian healthcare providers. Military prescription drug benefits are provided through three programs: military treatment facility outpatient pharmacies, TRICARE contractor retail pharmacies, and a national contractor's mail-order service.

110. TRICARE conditions payment for medical services and supplies on the requirement that the services or supplies "are medically necessary."[56] Medical services and supplies are deemed medically necessary under the controlling regulations if the frequency, extent, and type of medical services are "generally accepted . . . to be reasonable and adequate for . . . treatment."[57] Also excluded from TRICARE coverage are "unproven drugs" and "all services directly related to the unproved drug, device, or medical treatment or procedure."[58] TRICARE only covers off-label uses if there is a review for medical necessity and a demonstration from "medical literature, national organizations, or technology assessment bodies that the off-label use of the drug is a safe, effective, and in accordance with nationally accepted standards of practice in the medical community."[59]

[56] 32 C.F.R §§ 199.4(a)(1)(i), (b)(1), (g)(1).
[57] 32 C.F.R § 199.2.
[58] 32 C.F.R §§ 199.4(g)(15)(i), (iii).
[59] 32 C.F.R. § 199.4(g)(15)(i)(A).

D. CHAMPVA

111. CHAMPVA, administered by the Department of Veterans Affairs (the "VA"), provides healthcare coverage, including payment for certain prescription drugs, to qualified families of deceased or disabled veterans.

112. CHAMPVA conditions payment for medical services and supplies on the requirement that they "are medically necessary and appropriate for the treatment," and specifically excludes services and supplies that "are not medically necessary and appropriate . . . for the diagnosis or treatment of a covered condition."[60]

E. Other Federal Programs

113. In addition to Medicare, Medicaid, TRICARE, CHAMPVA, the federal government offers health benefits, including prescription drug coverage, including the Federal Employee Program, Mailhandlers, and other health benefit programs which have been the victims of Allergan's fraudulent scheme.

F. State and Local Government Health Care Programs

114. In addition to federal health care programs, numerous states and local governments offer benefits to employees, children, prisoners, and other benefit programs which have been the victims of Allergan's fraudulent scheme.

115. Claims for Vraylar submitted to Government Programs for the treatment of non-indicated conditions were ineligible for reimbursement and therefore false.

116. Moreover, Vraylar claims submitted to Government Programs which are tainted by kickbacks paid by Allergan were ineligible for reimbursement and therefore were false.

[60] 38 CFR § 17.272(a); I § 17.272(a)(1) (excluding from coverage "[s]ervices, procedures or supplies for which the beneficiary has no legal obligation to pay).

VI. BACKGROUND: VRAYLAR

117. Vraylar is the brand name for cariprazine. Cariprazine is an atypical antipsychotic which acts primarily as a D_3 receptor and D_2 receptor partial agonist, with high selectivity for the D_3 receptor. Vraylar comes in capsule form in varying strengths of 1.5mg, 3mg, 4.5mg, and 6mg.

A. Critical Differences between Bipolar Depression and Major Depressive Disorder

118. Even though they appear similar, MDD and Bipolar Depression are two distinct clinical conditions.[61] The latest Diagnostic and Statistical Manual of Mental Disorders (DSM), the DSM-5, defines the different diagnoses using MDD and Bipolar Depression using the following criteria.

119. To be diagnosed with MDD, the individual must be experiencing five or more of the following symptoms during the same 2-week period and at least one of the symptoms should be either (1) depressed mood or (2) loss of interest or pleasure:

1. Depressed mood most of the day, nearly every day.
2. Markedly diminished interest or pleasure in all, or almost all, activities most of the day, nearly every day.
3. Significant weight loss when not dieting or weight gain, or decrease or increase in appetite nearly every day.
4. A slowing down of thought and a reduction of physical movement (observable by others, not merely subjective feelings of restlessness or being slowed down).
5. Fatigue or loss of energy nearly every day.
6. Feelings of worthlessness or excessive or inappropriate guilt nearly every day.
7. Diminished ability to think or concentrate, or indecisiveness, nearly every day.
8. Recurrent thoughts of death, recurrent suicidal ideation without a specific plan, or a suicide attempt or a specific plan for committing suicide.

[61] *See* Bowden, *A different depression: clinical distinctions between bipolar and unipolar depression*, https://www.sciencedirect.com/science/article/abs/pii/S0165032703001940?via%3Dihub; Perlis *et al.*, Clinical Features of Bipolar Depression Versus Major Depressive Disorder in Large Multicenter Trials, https://ajp.psychiatryonline.org/doi/full/10.1176/appi.ajp.163.2.225.

120. To receive a diagnosis of depression, these symptoms must cause the individual clinically significant distress or impairment in social, occupational, or other important areas of functioning. The symptoms must also not be a result of substance abuse or another medical condition.

121. The DSM-5 defines Bipolar Disorders as a group of brain disorders that cause extreme fluctuation in a person's mood, energy, and ability to function:

- *Bipolar I disorder* is a manic-depressive disorder that can exist both with and without psychotic episodes
- *Bipolar II disorder* consists of depressive and manic episodes which alternate and are typically less severe and do not inhibit function
- *Cyclothymic disorder* is a cyclic disorder that causes brief episodes of hypomania and depression

122. To be diagnosed with Bipolar Disorder, a person must have experienced at least one episode of mania or hypomania. To be considered mania, the elevated, expansive, or irritable mood must last for at least one week and be present most of the day, nearly every day. To be considered hypomania, the mood must last at least four consecutive days and be present most of the day, almost every day. During this period, three or more of the following symptoms must be present and represent a significant change from usual behavior:

1. Inflated self-esteem or grandiosity
2. Decreased need for sleep
3. Increased talkativeness
4. Racing thoughts
5. Distracted easily
6. Increase in goal-directed activity or psychomotor agitation
7. Engaging in activities that hold the potential for painful consequences, *e.g.*, unrestrained buying sprees[62]

[62] Substance Abuse and Mental Health Services Administration. *DSM-5 Changes: Implications for Child Serious Emotional Disturbance* (Jun. 3, 2016) https://www.ncbi.nlm.nih.gov/books/NBK519712/table/ch3.t7/?report=objectonly.

123. The depressive side of Bipolar Disorder is characterized by a major depressive episode resulting in depressed mood or loss of interest or pleasure in life. The DSM-5 states that a person must experience five or more of the following symptoms in two weeks to be diagnosed with a major depressive episode:

1. Depressed mood most of the day, nearly every day
2. Loss of interest or pleasure in all, or almost all, activities
3. Significant weight loss or decrease or increase in appetite
4. Engaging in purposeless movements, such as pacing the room
5. Fatigue or loss of energy
6. Feelings of worthlessness or guilt
7. Diminished ability to think or concentrate, or indecisiveness
8. Recurrent thoughts of death, recurrent suicidal ideation without a specific plan, or a suicide attempt[63,64]

124. MDD is among the most common conditions affecting humankind. In the United States, about 7% of people will develop depression in any given year; there is around a 17%-20% lifetime risk. In contrast to unipolar MDD, Bipolar Disorder and subsequently Bipolar Depression is much less common, affecting somewhere in the neighborhood of 1%-2% of people over a lifetime.[65]

125. Yet, the number of patients is not the only difference between MDD and Bipolar Depression. Critically, the treatments differ depending on the condition and the choice of the

[63] Jessica Truschel, *Bipolar Definition and DSM-5 Diagnostic Criteria: Bipolar disorder defined by the criteria established by the American Psychiatric Association*, Psycom (Nov. 25, 2019), https://www.psycom.net/bipolar-definition-dsm-5/.

[64] Substance Abuse and Mental Health Services Administration. *DSM-5 Changes: Implications for Child Serious Emotional Disturbance* (Jun. 3, 2016), https://www.ncbi.nlm.nih.gov/books/NBK519712/table/ch3.t5/?report=objectonly.

[65] Stephen M. Strakowski, MD, *A Guide to Treating Unipolar and Bipolar Depression,* Medscape (November 14, 2016), https://www.medscape.com/viewarticle/871539; John J. Miller, MD, *Major Depressive Episode: Is It Bipolar I or Unipolar Depression?,* Psychiatric Times (July 31, 2018), https://www.psychiatrictimes.com/special-reports/major-depressive-episode-it-bipolar-i-or-unipolar-depression.

appropriate diagnosis and treatment is of the utmost importance because the medications used are powerful and come with dangerous side effects.[66]

126. The editor-in-chief of *Current Psychiatry* said that with new treatment options specifically for Bipolar Depression, "clinicians can now treat this type of depression without putting the patient at risk of complications that ensue when antidepressants approved only for MDD are used erroneously as monotherapy for Bipolar Depression."[67]

127. Given the greater number of people suffering from major depression compared to Bipolar Depression, Allergan was highly motivated to ensure that Vraylar could be sold for both conditions regardless of the treatment differences. As described herein, this led to Allergan promoting Vraylar for MDD despite not having an indication for that separate and distinct condition.

B. Atypical Antipsychotics Are Powerful Drugs with Dangerous Safety Risks

128. Second-generation antipsychotics, more commonly referred to as atypical antipsychotics, were developed in the early 1990s as alternatives to first-generation psychotics for the treatment of serious mental disorders, such as Schizophrenia and Bipolar Disorder. Schizophrenia is a severe, debilitating, and difficult-to-treat mental illness afflicting around 1% of the U.S. population and characterized by disorganized and delusions, hallucinations, disorganized speech, and grossly disorganized or catatonic behavior.[68]

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[66] W. David Robinson, PhD, Jenenne A. Geske, PhD, Layne A. Prest, PhD, and Rachel Barnacle, MS, *Depression Treatment in Primary Care*, Journal of the American Board of Family Medicine (October 15, 2004) https://www.jabfm.org/content/jabfp/18/2/79.full.pdf ("Although combination treatment is recommended for both depression and Bipolar Disorder, the suggested pharmacotherapy regimens for these 2 mood disorders are different. Therefore, a correct diagnosis is critical.").

[67] Henry A. Nasrallah, MD, *Misdiagnosing Bipolar Depression as major depressive disorder*, Current Psychiatry, 2013 October; 12(10): 20-21, https://mdedge-files-live.s3.us-east-2.amazonaws.com/files/s3fs-public/Document/September-2017/020_1013CP_FromTheEditor_FINAL.pdf.

[68] *See* DSM-V 295.90.

129. Beginning in the 1950s, the primary treatments for Schizophrenia and Bipolar Disorder were first-generation antipsychotics such as haloperidol, thioridazine, and chlorpromazine, which function by blocking dopamine receptors in the brain. Although effective, first-generation antipsychotics share serious adverse events, among the most serious of which are extrapyramidal motor control disabilities such as unsteady, Parkinsonian-type movements and Akathisia, where the patient is unable to remain still. Long-term use may also lead to tardive dyskinesia, characterized by repetitive, involuntary tics and movements, which in many cases continue permanently even following the patient's discontinuation of the drug.

130. The second-generation or atypical antipsychotics were developed in the 1990s in an attempt to achieve the efficacy benefit of typical antipsychotics while lessening their safety burden. In doing so, atypical antipsychotics were at least partly successful. Second-generation antipsychotics are generally perceived as safer than first-generation drugs, in large part due to the decreased incidence of extrapyramidal side effects, and as a result second-generation antipsychotics now account for about 90% of all prescribed antipsychotics.

131. That atypical antipsychotics are considered safer than typical antipsychotics, however, does not imply that atypical antipsychotics are completely safe. On the contrary, use of atypicals including Vraylar is accompanied by the risk of numerous adverse events, among the most serious of which are metabolic abnormalities that regularly lead to diabetes and weight gain; cardiac disorders; extrapyramidal side effects; and cognitive impairment. In addition, use of each drug is accompanied by significant risks of hypotension, elevated liver enzymes (an indicator of liver damage), abdominal pain, constipation, dizziness, somnolence, and a litany of other cardiac, digestive, musculoskeletal, and nervous system adverse events.

132. In January 2009, a study published in the New England Journal of Medicine found that patients taking atypical antipsychotics experienced a risk of sudden cardiac death that was more than double that of the ordinary population.[69] In fact, the risk of sudden cardiac death for patients on atypical antipsychotics exceeded even that for patients on typical antipsychotics.[70] While Vraylar was not part of the study, as a similar atypical antipsychotic the risks identified by the study still apply.

133. Nonetheless, the perception that atypical antipsychotics are safe—more so than they actually are—has been a major contributor to the dramatic increase in prescribing of atypical antipsychotics for a litany of unsafe and ineffective conditions including Akathisia, agitation, aggression, anxiety and generalized anxiety disorder, behavioral disorders (including ones related to dementia), psychotic episodes, obsessive behavior, unipolar depression, major depressive disorder, obsessive compulsive disorder, post-traumatic stress disorder ("PTSD"), personality disorders, and Tourette's Syndrome.

134. As alleged below, Allergan's sales representatives' materially misleading minimization of Vraylar's safety risks in their promotions to health care professionals was an integral driver of health care professionals' unjustified assessment of its safety and those health care professionals' subsequent prescribing of Vraylar for conditions for which it is not safe and/or effective.

C. Vraylar's Checkered Clinical Research History and Label Evolution

[69] Ray, et al., *Atypical Antipsychotic Drugs and the Risk of Sudden Cardiac Death*, 360 New Eng. J. Med. 225 (2009).
[70] *Id.*

135. Throughout the history of Vraylar, Allergan has been determined to expand the indications for Vraylar despite concerns, including serious concerns from the FDA, about its efficacy for certain conditions and serious side effects.

1. Vraylar Approval for Schizophrenia and Bipolar Disorder Despite Initial FDA Rejection

136. On November 28, 2012, Forest Laboratories first submitted a New Drug Application ("NDA") for cariprazine to the FDA. The NDA was for both Schizophrenia and manic or mixed episodes associated with Bipolar I Disorder and followed the results of three placebo comparison trials each for both diagnoses.[71] These studies, funded by Forest Laboratories, showed that while cariprazine showed promise for treating Schizophrenia and manic/mixed episodes with Bipolar I disorder, the drug had significant side effects.

137. In particular, all three studies for Schizophrenia showed a substantial increase in instances of Akathisia. Akathisia is a movement disorder characterized by a feeling of inner restlessness and inability to stay still. Those affected may fidget, rock back and forth, or pace, while some may just have an uneasy feeling in their body. The most severe cases may result in aggression, violence or suicidal thoughts.

138. NCT01104779 showed that 3.4% of study participants experienced Akathisia while using the placebo, but with the use of cariprazine 3-6mg/per day that percentage rose to 15.89% and for those using cariprazine 6-9mg/day the percentage rose to 16.89%. The one published study on Schizophrenia found that the incidence of Akathisia was "twice the rate of placebo…in the 6

[71] Schizophrenia studies were: NCT01104779 (April 15, 2010 to December 15, 2011); NCT00694707 (June 10, 2008 to August 31, 2009); NCT01104766 (April 15, 2010 to December 20, 2011). The Manic or Mixed Episodes Bipolar I studies were NCT01058668 (January 29, 2010 December 2011); NCT01058096 (January 28, 2010 to July 2011); NCT00488618 (June 20, 2007 to July 2008). *See NDA Submitted for Cariprazine*, Drugs.com (Nov. 28, 2012), https://www.drugs.com/nda/cariprazine_121128.html.

mg/d group…[and the] incidence of akathisia was significantly greater for cariprazine 6 mg/d (14.6%) versus placebo (4.6%; $P = .0034$)."[72]

139. Likewise, multiple studies for manic/mixed episodes also found a connection between Akathisia and cariprazine. NCT01058668 found that at 6-12mg/day the incidence of Akathisia was 22.94%, considerably higher than the placebo rate of 4.97%.[73] Likewise, NCT01058096 found an increase in the incidences of Akathisia from 5.19% for the placebo group to 22.15% in the cariprazine group.[74] NCT01058096 also found an increase in the incidences of extrapyramidal disorder from 1.95% for the placebo group to 15.19% in the cariprazine group. Similarly, NCT00488618 found an increase in the incidences of Akathisia from 6.78% for the placebo group to 19.49% in the cariprazine group.[75] NCT00488618 also found an increase in the incidences of extrapyramidal disorder from 11.02% for the placebo group to 24.58% in the cariprazine group.

140. On November 21, 2013, the FDA denied the NDA for Vraylar via a response letter to Forest Laboratories and Gedeon Richter. As the FDA stated: "Akathisia and other extrapyramidal symptoms were among the most common and most clinically significant adverse reactions in the cariprazine program. Even at the lowest cariprazine doses (1.5 mg and 3 mg), Akathisia was reported for 10.3% of subjects, compared to 4.1% of the placebo group and 8.6% of the risperidone group. Akathisia was reported for 18.1% of subjects in the high-dose cariprazine group (9 mg and 12 mg) and 14.2% of the intermediate dose group (4.5 mg and 6 mg)." While it

[72] *Safety and Efficacy of Cariprazine in Patients With Schizophrenia* (NCT01104766), https://clinicaltrials.gov/ct2/show/NCT01104766.
[73] *Safety and Efficacy of Cariprazine for Bipolar I Disorder* (NCT01058668), https://clinicaltrials.gov/ct2/show/NCT01058668.
[74] *Safety and Efficacy of Cariprazine for Mania* (NCT01058096), https://clinicaltrials.gov/ct2/show/NCT01058096.
[75] *Study Evaluating Cariprazine (RGH-188) in the Treatment of Patients With Acute Mania* (NCT00488618), https://clinicaltrials.gov/ct2/show/NCT00488618.

acknowledged the drug's effectiveness in the treatment of both diagnoses, the FDA denied the NDA due to concerns about the safety of cariprazine.[76]

141. The FDA was particularly concerned about Akathisia because, as it explained, "Akathisia can be one of the most serious adverse reactions related to antipsychotic treatment. At its most severe, it is an intense subjective sense of inescapable motor tension and restlessness, often accompanied by acute anxiety, agitation, and exacerbation of psychotic or manic symptoms. Akathisia can lead to suicide and other dangerous behavior." In another letter, FDA once again reiterated the seriousness of Akathisia: "Akathisia is a particularly disturbing adverse reaction for patients to experience; it has been linked to suicide."[77]

142. With regard to Allergan's cariprazine trials specifically, the FDA stated that: "Akathisia is evident even at the low doses and is higher than the percentage seen with aripiprazole (the approved drug with the most obvious association with akathisia to date) as the comparator in this trial (although the percentage of Akathisia from aripiprazole labeling is 8-13 percent). Dr. Levin has made the point in his review that Akathisia is a "very disturbing adverse reaction for patients, and that if left untreated it can lead to suicide and other dangerous behavior (motor restlessness, pacing, intentional self-injury, violence directed at others)."[78]

143. Despite the concerns, Actavis and Gedeon Richter resubmitted their NDA to the FDA on January 6, 2015 with new trial results.[79] For Schizophrenia, in NCT01412060 (August 8,

[76] *Forest Laboratories and Gedeon Richter Receive Complete Response Letter for Cariprazine,* Drugs.com (Nov. 21, 2013), https://www.drugs.com/nda/cariprazine_131121.html.
[77] FDA Center for Drug Evaluation and Research, "APPLICATION NUMBER 204370Orig1Orig2s000: Other Action Letters" (Nov. 19, 2013).
[78] FDA Center for Drug Evaluation and Research, "APPLICATION NUMBER 204370Orig1Orig2s000: Summary Review" (Sept. 16, 2015).
[79] *Actavis and Gedeon Richter Announce FDA Receipt of NDA Resubmission for Cariprazine*, Drugs.com (Jan 6. 2015), https://www.drugs.com/nda/cariprazine_150106.html.

2011 to September 2014), cariprazine was found to have higher remission rates, longer sustained remission duration, and increased likelihood of sustaining remission for ≥6 consecutive months versus placebo.[80] NCT01104792 (May 2010 to January 31, 2013) found that cariprazine was generally safe and well tolerated in the long term treatment of Schizophrenia.[81]

144. The FDA approved Vraylar for the acute treatment of manic or mixed episodes associated with Bipolar I Disorder and the treatment of Schizophrenia on September 17, 2015.[82] The 2015 label was indicated for: (1) "Treatment of Schizophrenia," and (2) "Acute treatment of manic or mixed episodes associated with bipolar I disorder."

2. The Vraylar Label Clearly States There is No Evidence to Support Its Use in Treating Pediatric and Elderly Patients

145. In the 2015 approval letter, the FDA waived the "pediatric study requirement for ages 0 to 9 years for the treatment of manic or mixed episodes associated with Bipolar I Disorder and 0 to 12 years for the treatment of Schizophrenia because necessary studies are impossible or highly impractical due to the low incidence of these disease states in these age ranges." They also allowed the adolescent studies to be deferred because the product was ready for use in adults.[83]

[80] Christoph Correll, MD, et al., *Long-Term Remission With Cariprazine Treatment in Patients With Schizophrenia: A Post-Hoc Analysis of a Randomized, Double-Blind, Placebo-Controlled, Relapse Prevention Trial*, Psych Congress (Sept. 16-19, 2017), https://www.psychcongress.com/posters/long-term-remission-cariprazine-treatment-patients-Schizophrenia-post-hoc-analysis.
[81] HA Nasrallah, *et al.*, *The safety and tolerability of cariprazine in long-term treatment of schizophrenia: a post hoc pooled analysis*, BMC Psychiatry. 2017 Aug 24;17(1):305, https://www.ncbi.nlm.nih.gov/pubmed/28836957?dopt=Abstract.
[82] *FDA Approves Vraylar*, Drugs.com (Sept. 17, 2015), https://www.drugs.com/newdrugs/fda-approves-vraylar-cariprazine-Schizophrenia-bipolar-disorder-4264.html.
[83] FDA, "NDA Approval" (Sept. 17, 2015), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/204370Orig1Orig2s000ltr.pdf

146. The label reflects this lack of pediatric testing. It said "Safety and effectiveness in pediatric patients have not been established. Pediatric studies of VRAYLAR have not been conducted."[84]

147. The label also came with a black box warning cautioning against use in elderly patients: "Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. VRAYLAR is not approved for the treatment of patients with dementia-related psychosis."[85]

3. Vraylar Fails to Demonstrate Efficacy and Safety Necessary for MDD Indication

148. After successfully obtaining Schizophrenia and Bipolar Disorder indications for Vraylar, Allergan turned its sights to the much larger and more lucrative MDD market. To that end, Allergan funded a series of studies to determine the safety and efficacy of Vraylar to treat MDD as an adjunctive therapy.

149. The first completed Phase 2 study of cariprazine to treat MDD (NCT00854100) "did not show statistically significant superiority to placebo in any efficacy measures."[86] Conducted in 2009-2010, NCT00854100 was a 19-week, multicenter, randomized, double blind, placebo-controlled, parallel-group study of adjunctive cariprazine 0.1–0.3 and 1.0–2.0 mg/day in outpatients with MDD who had failed to respond to one or two previous antidepressant therapies given at adequate dose and titration (protocol MD-71; NCT00854100).

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[84] Vraylar Label (September 2015), https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/204370lbl.pdf.
[85] *Id.*
[86] *Safety and Efficacy of Cariprazine As Adjunctive Therapy In Major Depressive Disorder* (NCT00854100), https://clinicaltrials.gov/ct2/show/NCT00854100.

150. A second Phase 2 study, NCT01469377, was conducted from November 2011-December 2013 to evaluate the efficacy of cariprazine to treat MDD.[87] The study found promising results for the use of cariprazine to treat MDD, but also found that cariprazine's use came with increases in significant side effects and noted the need more further clinical studies. NCT01469377 was a multicenter, randomized, double-blind, placebo-controlled, parallel-group study adjunctive flexible-dose cariprazine in adults with MDD and inadequate response to ongoing antidepressant treatment. The study concluded that that adjunctive cariprazine 2–4.5 mg/d was effective and generally well tolerated in adults with MDD who had inadequate responses to standard antidepressants. But there were significant side effects found with the higher doses of cariprazine (2-4.5mg). Consistent with the other studies, the incidences of Akathisia increased from 2.26% in the placebo group to 22.34% in the cariprazine (2-4.5mg) group. The incidences of insomnia increased from 6.39% in the placebo group to 13.92% in the cariprazine (2-4.5mg) group. The incidences of nausea increased from 4.89% in the placebo group to 12.82% in the cariprazine (2-4.5mg) group. Ultimately, the study's authors concluded that while promising, "[f]urther clinical studies to confirm these results are warranted."

151. The follow-up study, a Phase 3 trial of cariprazine to treat MDD (NCT01715805), took place from 2012 to 2016.[88] The study found a lack of significant improvement in depressive symptoms along with newly-emergent adverse events including Akathisia and restlessness. The study concluded: "A greater proportion of participants achieved MADRS[89] response with

[87] *Safety and Efficacy of Cariprazine as an Adjunctive to Antidepressant Therapy in Major Depressive Disorder* (NCT01469377), https://clinicaltrials.gov/ct2/show/NCT01469377.

[88] WD Early, *et al., Cariprazine Augmentation to Antidepressant Therapy in Major Depressive Disorder: Results of a Randomized, Double-Blind, Placebo-Controlled Trial*, Psychopharmacol Bull. 2018 Jun 20;48(4):62-80, https://www.ncbi.nlm.nih.gov/pubmed/30618475?dopt=Abstract.

[89] MADRS refers to the Montgomery–Åsberg Depression Rating Scale ("MADRS"), a ten item diagnostic questionnaire which psychiatrists use to measure the severity of depressive episodes in patients with mood

cariprazine vs placebo, but differences were not significant.... The lack of significant improvement in depressive symptoms with adjunctive cariprazine and ADT [antidepressant therapy] for MDD in inadequate responders contrasts with previously published results, therefore additional studies are needed to understand role of adjunctive cariprazine in MDD." The study was a 18- to 19-week, multicenter, randomized, double-blind, placebo-controlled, parallel-group, flexible-dose study of adjunctive cariprazine 1.5–4.5 mg/d with open-label ADT.

152. Beyond the lack of efficacy to treat MDD, the study found a significant increase in the incidence of adverse events in the cariprazine group compared to the control group.[90] Once again, "Akathisia occurred more frequently in participants in the cariprazine group (17.1%) compared to placebo (3.1%). Treatment-emergent parkinsonism (SAS score 3 at baseline and >3 postbaseline) was observed more often in cariprazine participants (4.5%) than placebo (0.4%). Treatment-emergent akathisia (BARS score 2 at baseline and >2 postbaseline), occurred more frequently in cariprazine (21.7%) vs placebo (2.7%) participants."

153. On August 5, 2016, Allergan and Gedeon Richter reported this failure to obtain clinical trial support for an MDD indication for Vraylar. Although the study missed its primary endpoint, Allergan said it remained optimistic and stated its intent to move forward with another Phase III study.[91]

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disorders. It was designed in 1979 by British and Swedish researchers as an adjunct to the Hamilton Rating Scale for Depression (HAMD) which would be more sensitive to the changes brought on by antidepressants and other forms of treatment than the Hamilton Scale was.

[90] *Efficacy, Safety and Tolerability of Cariprazine as an Adjunctive Treatment to Antidepressant Therapy (ADT) in Patients With Major Depressive Disorder (MDD)* (NCT01715805), https://clinicaltrials.gov/ct2/show/NCT01715805.

[91] Nick Taylor, *Allergan and Richter push ahead despite PhIII fail for depression drug*, FierceBiotech (Aug. 8, 2016), https://www.fiercebiotech.com/biotech/allergan-and-richter-push-ahead-despite-phiii-fail-for-depression-drug.

154. An additional study was conducted as a follow up on NCT01715805. The follow-up study, NCT01838876, found that in patients with MDD, cariprazine was generally safe and well tolerated when used as adjunctive treatment to anti-depressant treatment.[92] NCT01838876 was a Phase 3 trial conducted from April 29, 2013 to July 27, 2015. While NCT01838876 did provide some positive results, it was very limited especially when compared to NCT01715805 (the 2016 double-blind, placebo-controlled study finding no significant improvement in depressive symptoms). As the study's authors acknowledged: "The limitations of the study include the open-label study design, and the absence of a placebo-comparator or an active-comparator group. Although the flexible-dose regimen more closely mimics real-world clinical practice, it limits the ability to draw conclusions on dose–response relationships for safety parameters."

155. Overall, the numerous studies did not support the use of Vraylar for the treatment of MDD.[93] In fact, beyond the lack of treatment efficacy, the studies showed that the use of cariprazine came with a marked increase in serious side effects, especially at higher dosages.

4. Allergan Gains Bipolar I Depression Indication

156. Despite the failure of the trials of cariprazine for use to treat MDD, Allergan pushed ahead to gain approval for use for use of cariprazine for Bipolar I Depression. Three studies were conducted on the use of cariprazine for Bipolar I Depression.

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[92] Eduard Vieta, *et al.*, *Long-term safety and tolerability of cariprazine as adjunctive therapy in major depressive disorder*, International Clinical Psychopharmacology 34(2):1 (Dec. 2018), https://www.researchgate.net/publication/329480748_Long-term_safety_and_tolerability_of_cariprazine_as_adjunctive_therapy_in_major_depressive_disorder .

[93] Allergan's additional failures in its attempts to enter the MDD market with its drug Rapastinel only further incentivized the off-label promotion of Vraylar. In three acute studies (RAP-MD-01,-02,-03), the rapastinel treatment arms "did not differentiate from placebo on the primary and key secondary endpoints," in patients with major depressive disorder, Allergan said. *See* Selina McKee, *Allergan's rapastinel fails to hit key targets in depression trials*, PharmaTimes (March 7, 2019) http://www.pharmatimes.com/news/allergans_rapastinel_fails_to_hit_key_targets_in_depression_trials_1280697.

157. NCT01396447 was an 8-week multinational, multicenter, randomized, double-blind, placebo-controlled, parallel-group, fixed-dose study in adult patients with Bipolar I Disorder experiencing a current major depressive episode.[94] The study found that "Efficacy for cariprazine at 1.5 mg/day compared with placebo was demonstrated by significant improvement on every efficacy measure. An efficacy signal was detected for the 3.0-mg/day dosage, but this dosage was not significantly superior to placebo when adjusted for multiplicity. The 0.75-mg/day dosage was not significantly different from placebo on most measures."

158. Like other cariprazine studies, NCT01396447 also found the incidence of Akathisia was higher with cariprazine than placebo, rising from 1.38% in the placebo group to 2.84% in the .75mg cariprazine group, 4.79% in the 1.5mg cariprazine group, and up to 14.38% in the 3mg cariprazine group. The study was also limited by the lack of an active comparator, short treatment duration, and was not powered to detect a potential dose response, so it is unknown whether there is a relationship between cariprazine dosage and therapeutic effect.

159. The other two studies, NCT02670551 and NCT02670538, also found that cariprazine 1.5 mg dose demonstrated statistical significance over placebo.[95] Additionally, in NCT02670551, the Vraylar 3 mg dose demonstrated statistical significance over placebo. Common adverse events reported in the pivotal trials were nausea, Akathisia, restlessness, and extrapyramidal symptoms.

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[94] *Safety, Tolerability, and Efficacy of Cariprazine in Participants With Bipolar Depression* (NCT01396447), https://clinicaltrials.gov/ct2/show/NCT01396447.

[95] *Study on the Efficacy, Safety, and Tolerability of Cariprazine Relative to Placebo in Participants With Bipolar I Depression* (NCT02670551), https://clinicaltrials.gov/ct2/show/NCT02670551; *Study of the Efficacy of a Fixed-dose Regimen of Cariprazine Compared to Placebo for Treatment of the Depressive Episode in Participants With Bipolar I Disorder* (NCT02670538), https://clinicaltrials.gov/ct2/show/NCT02670538.

160. NCT02670538 also found the incidence of Akathisia was higher with cariprazine than placebo, rising from 1.82% in the placebo group to 5.39% in the 1.5mg cariprazine group and 9.49% in the 3mg cariprazine group.

161. Due do these trials' success, on May 28, 2019, Vraylar was approved for the treatment of depressive episodes associated with Bipolar I Disorder (Bipolar Depression) in adults.[96]

162. As a result, the label added the new indication of treatment of depressive episodes associated with Bipolar I Disorder (Bipolar Depression).

163. The current label for Vraylar states the following in the "Indications and Usage" Section:

> VRAYLAR is an atypical antipsychotic indicated for the:
> • Treatment of Schizophrenia in adults (1)
> • Acute treatment of manic or mixed episodes associated with bipolar I disorder in adults (1)
> • Treatment of depressive episodes associated with bipolar I disorder (Bipolar Depression) in adults (1)

164. Vraylar has never had an indication for any other conditions, including major depressive disorder (MDD).

165. New warnings also were added to the label in 2019. Notably, the Black Box Warning added a warning about the use of Vraylar in pediatric patients given the risks and lack of demonstrated efficacy:

[96] *FDA Approves Expanded Use of Vraylar (cariprazine) in the Treatment of Bipolar Depression*, Drugs.com (May 28, 2019), https://www.drugs.com/newdrugs/fda-approves-expanded-vraylar-cariprazine-bipolar-depression-4983.html.

WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS; and SUICIDAL THOUGHTS AND BEHAVIORS

See** full prescribing information **for complete boxed warning.

- **Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. VRAYLAR is not approved for the treatment of patients with dementia-related psychosis. (*5.1*)**
- **Antidepressants increased the risk of suicidal thoughts and behaviors in pediatric and young adult patients. Closely monitor all antidepressant-treated patients for clinical worsening and emergence of suicidal thoughts and behaviors. Safety and effectiveness of VRAYLAR have not been established in pediatric patients (5.2, 8.4)**

166. "Suicidal Thoughts and Behaviors in Children, Adolescents and Young Adults" and "Metabolic Changes" were also added to the Warnings and Precaution section.[97] As that section illustrates, "[i]n pooled analyses of placebo-controlled trials of antidepressant drugs (SSRIs and other antidepressant classes) that included approximately 77,000 adult patients and 4,500 pediatric patients, the incidence of suicidal thoughts and behaviors in antidepressant-treated patients age 24 years and younger was greater than in placebo-treated patients."

167. As with the original label, and in addition to the black box warning, the current Vraylar label notes that the use of Vraylar in pediatric populations is untested. As the label says, "[s]afety and effectiveness in pediatric patients have not been established. Pediatric studies of VRAYLAR have not been conducted. Antidepressants increased the risk of suicidal thoughts and behaviors in pediatric patients."

168. Thus, the label itself makes clear that there are considerable risks for use of Vraylar in pediatric and young adult populations. In fact, a trial for Vraylar's effectiveness in the treatment of

[97] Vraylar Label (May 2019), https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/204370s006lbl.pdf.

children and adolescents for any of its indications has yet to be completed, and the existing studies show the considerable risk of using powerful antidepressant drugs in these populations.[98]

D. Vraylar's Launch in the Atypical Antipsychotics Market

169. Since its launch in late 2015, Vraylar has quickly become a blockbuster drug and a major competitor in the atypical antipsychotic market, particularly since the FDA's recent 2019 approval of Vraylar for the treatment of Bipolar Depression. In the fourth quarter of 2019, Vraylar's net revenues were $283.1 million, an increase of 88.1% from the prior year's fourth quarter. For full-year 2019, Vraylar net revenues were $857.5 million, an increase of 76% from 2018.[99]

170. In the United States, the wholesale cost per month for Vraylar oral capsule (1.5 mg – 3mg) is about $306.00 for a supply of seven (7) capsules.

171. Government Programs' spending on Vraylar has steadily increased since the launch of Vraylar. In 2016, CMS reported that total Medicaid spending on Vraylar was $22,376,522.78 and in 2017 it increased to $85,961,782.79. By 2018, the total spending had risen to $166,296,359. Similarly, CMS reported that Medicare Part D's total spending on Vraylar increased from $26,569,156.52 in 2016 to $95,536,917.06 in 2017, and finally, to a high of $184,939,872 in 2018, the last full year of available payment data. These spending numbers are expected to dramatically increase given Allergan's intense marketing scheme, much of it for off-label uses.

VII. ALLERGAN'S FRAUDULENT OFF-LABEL MARKETING SCHEME

172. The dramatic increase of Vraylar sales across the country is due in no small part to Allergan's illegal off-label promotion of the drug. As part of its deliberate scheme to conceal its

[98] There is an ongoing study on Vraylar's use in adolescents with Schizophrenia (NCT03817502) which is estimated to be completed by December 17, 2022.
[99] Allergan 8-K 4Q '19 (February 10, 2020), https://www.allergan.com/investors/quarterly-results.

off-label promotion of Vraylar and in order to maintain a façade of compliance, Allergan ensured that all official promotional materials, such as visual sales aids and printed training materials were approved, and on several (but not all) occasions instructed sales representatives not to discuss unapproved uses in e-mails or in call notes. However, during district meetings, phone calls with managers, and ride-alongs between sales representatives and managers – and essentially in any forum in which Allergan could do so surreptitiously – Allergan repeatedly directed sales representatives to promote Vraylar for off-label uses.

173. To ensure the successful launch of the drug, and continued success after gaining new indications, Allergan instructed and encouraged its sales representatives to promote Vraylar for off-label uses like anxiety and major depressive disorder and to request health care professionals to replace competitor drugs like Abilify with Vraylar, despite the fact that these other drugs have different FDA approved indications.

174. Allergan's off-label promotion of Vraylar thus has caused health care professionals to prescribe the drug for non-medically accepted uses, and as a result caused the submission of false claims to Government Programs. As the foreseeable result of Allergan's illegal conduct, Government Programs paid substantial reimbursements for Vraylar claims that were ineligible for reimbursement and therefore false.

175. When Relator began working at Allergan in 2018, he was trained, including during ride-alongs with district managers and during sales meetings, to promote Vraylar for off-label uses. During promotional speaker events, company-sponsored training sessions, and on sales calls to health care professionals, Relator witnessed the Allergan managers and sales representatives promoting Vraylar for these off-label uses and observed those health care professionals' increased prescribing of Vraylar for off-label uses as a result.

A. Allergan's Sales Organization Incentivized Illegal Off-Label Promotion

176. Allergan's retail sales division was responsible for promoting Vraylar. Within retail sales, Allergan organized its sales teams into different groups depending on the products they promoted. For example, there is an Aesthetic Sales Group that sells Botox.

177. Relevant here, two different Allergan sales groups had responsibility for promoting Vraylar. The primary responsibility for Vraylar's promotion was with Specialty Sales Group otherwise known as the Central Nervous System (CNS) Group. Consisting of approximately 30 District Managers (DMs) and 280 sales representatives, the CNS sales group was responsible for promoting only Vraylar and Viibryd. The other sales group that promoted Vraylar was the Clinical Sales Representatives Group (CSR), which had sales representatives who largely called on primary care physicians (PCPs). Consisting of approximately 83 DMs and 800 sales representatives, many in the CSR group promoted Vraylar in addition to the CNS group.

178. The sales representatives in Relator's region primarily called on psychiatrists, with about 10% of their calls going to PCPs. The CNS group calling on PCPs was in addition to Allergan having its CSR group, which largely focused on PCPs.

179. The CNS sales group was awarded sales bonuses on a quarterly basis. The bonuses paid were weighted heavily on the sales of Vraylar: Vraylar determined 70% of the bonus and Viibryd determined 30%. The bonus was determined by percentage of attainment of sales goals. The goals increased quarterly, and never went down. The sales goals made no distinction between sales for unapproved uses and approved uses. Essentially, Allergan considered a sale a sale.

180. While in the field with his manager, DM Burrier mentioned to Relator a strategy that Sunovion, the manufacturer of Vraylar competitor Latuda, had in place to prevent its sales representatives from selling off-label. Burrier commented that, to reduce the potential risk that its

sales representatives would promote Latuda illegally off-label, the company paid representatives a commission only for the approved indication of Bipolar Depression. To implement this plan, Sunovion looked at the ICD-10 code of the Latuda prescription which would show a different code for approved uses (e.g., Bipolar Depression) and for unapproved uses (e.g., MDD/bipolar manic/mixed episodes). Using Sunovian checks and balances incentive bonus structure meant that sales representatives would not get sales credit for off-label prescriptions (prescriptions with an ICD-10 code that Latuda was NOT approved for), thereby reducing any incentive to promote Latuda for unapproved uses.

181. Allergan could have easily put such a system in place for Vraylar, but it has not. To the contrary, Allergan has actively and intentionally instructed its sales representatives to promote Vraylar for off-label uses, putting sales numbers above all else and thereby placing its sales representatives in the untenable position of committing health care fraud.

182. On one of Relator's first Field Coaching Reports after starting at Allergan, the priorities of Relator's manager and Allergan are spelled out clearly: "Everything should be centered around one thing and that's growing prescriptions. Every move or decision you make should be centered around this."

183. Allergan's compensation model rewarded top selling sales representatives very generously. Sales representatives in the Top 25% of the sales rankings could make $35,000+ per quarter in 2019 from bonus and "bonus kicker" programs.

184. Allergan continuously updated the rankings of the sales representatives' percentage toward attainment to their sales goals. The sales representatives could check these numbers on a real-time basis to assess their standing in their region – *e.g.,* sales representatives could see that they were ranked #10 out of 65 for percentage to goal on a particular day. While the sales

representatives could not see their numerical ranking overall on a national level, they could compare their percentage to goal to the national average in real time.

185. The combination of the large financial incentives and Allergan's treatment of all sales equally meant that its sales representatives were highly motivated and incentivized to promote drugs like Vraylar off-label. In fact, Allergan encouraged the practice. The amount of money a sales representative could make was always brought up by managers; helping patients' lives, compliance and reporting of adverse events were rarely discussed.

B. The Endemic Culture of Non-Compliance at Allergan

186. Allergan publicly holds itself out as committed to high ethical standards, as well as being compliant with fraud, waste and abuse laws enacted to prevent fraud, overutilization, over-billing, and safeguard the health and safety of Government Program beneficiaries. Yet as this Complaint demonstrates, the reality is far different.

187. Allergan touts its compliance policies in a 55-page "Code of Conduct" entitled "Leading with Integrity."[100] The Code hits on all the buzzwords and concepts associated with corporate compliance, from ensuring patient safety to being compliant with government rules and regulations.

188. In its Code of Conduct, Allergan says it "never jeopardize[s] patient safety, product quality or compliance." In a section entitled "Product Promotion" Allergan touts its compliance with the law surrounding off-label promotion specifically:

> Patients and physicians rely on our company to promote our products honestly and in accordance with the law. We ensure that the information we provide in our promotional materials and communications is accurate, reliable and balanced.

[100] *See generally* Code of Conduct, Allergan plc (2020), https://www.allergan.com/investors/corporate-governance.

189. Allergan lays out five points of emphasis for how it allegedly promotes its products "responsibly":

> **Focus on patient safety**: Where applicable, ensure that patient safety is included in any promotional effort or activity in which we engage.
>
> **Represent our products fairly**: Advertise and promote our products using only approved materials and information that has been reviewed by Allergan personnel for compliance with laws and regulations.
>
> **Be transparent**: Provide complete, fair and balanced information about the benefits and risks of our products. Make sure that any information you provide can be supported by scientific data.
>
> **Choose integrity**: Follow applicable laws and regulations. Conduct promotional activities ethically and never offer a financial or other advantage to obtain or retain business.
>
> **Remain consistent with locally approved labels**: Promote only truthful, non-misleading, on-label information about our products when participating in advertising activities or interacting with physicians, healthcare professionals and other customers.

190. In addition to the Code of Conduct, Allegan has an internal corporate policy entitled "Reporting Adverse Events and Other Safety Information." The policy articulates what Allergan allegedly requires from its employees regarding the reporting of adverse events. Allergan acknowledges that it "has an ethical and legal responsibility to collect and analyze all safety-related information regarding Allergan's products."

191. The Adverse Events Policy makes it clear that it "applies company-wide to all colleagues" and that the responsibility for reporting adverse events and complying with Allergan's policy falls on all employees, including managers.

192. The Adverse Events Reporting Policy also lays out in detail what sort of information needs to be collected if an employee learns of a potential adverse event. The types of information include patient identifiers, reporter details, details about the potential adverse event

(with instructions to "be specific as possible"), and product information (again with instructions to "be as specific as possible"). Additionally, the policy requires reporting of this information within 24 hours.

193. Allergan's compliance documents were a façade only and belie how it actually has been selling Vraylar. Indeed, Allergan took steps to conceal its off-label promotion by removing discussion of off-label uses from training materials, visual sales aids, field coaching reports, and promotional speaker slide decks. Further, during national and regional sales meetings, Allergan limited training to Vraylar's approved indications and even purported to instruct sales representatives to exclude illegal off-label discussions from its promotional details to health care professionals. In reality, this conduct was just an effort to conceal Allergan's fraudulent scheme.

194. As demonstrated in this Complaint, however, the concepts and policies in documents like Allergan's Code of Conduct or its facially-compliant sales aids are nothing more than policies on paper. In actual practice, prohibitions on illegal sales conduct were meaningless, and managers explicitly instructed sales representatives to ignore them. Allergan did not "lead with integrity" but in reality routinely violated the law in addition to its own Code of Conduct.

195. Soon after Relator was hired, he saw first-hand that Allergan was much less concerned about compliance than the other pharmaceutical companies where Relator worked previously. Instead of being concerned with helping patients within the confines of the law, Allergan was only concerned with hitting sales goals and sales numbers.

196. Relator's first days at Allergan demonstrated this problematic culture immediately. All sales employees were supposed to complete Allergan's on-boarding process, which included a "Home Study Agenda." The Home Study Agenda was supposed to be completed over the course

of fifteen days and included important modules on compliance, adverse event reporting, and Allergan's own code of conduct.

197. Yet, Relator's DM, Garrett Burrier, was more concerned with his representatives getting into the field quickly and selling any way possible rather than learning the compliance and safety training. To that end, DM Burrier cut the scheduled time allotted for the Home Study Program nearly in half to a mere eight days for both Relator and two other new hires in the district. After Relator talked with the two other sales representatives, they all agreed that none of them felt comfortable or ready to be out in the field selling powerful drugs like Vraylar, despite the directive from their DM.

198. During the time when Relator was supposed to be working through the training modules, his DM had a meeting with Relator and two other new hires, Matt Munson, a sales representative for Minnesota and Matt Griffin, a sales representative based out of South Dakota. The purpose of the meeting was to "certify" the sales representatives to be able to sell in the field before going to formal home office training. The certification process consisted of meeting for just a half-day, reviewing some of the training materials, asking questions, and looking over some sales aids. There was no role playing, nor practice using the sales aid, as was common in most training Relator had previously at other companies. Instead, the training was mostly informal with managers just trying to get the sales representatives pumped up about selling – not a serious check to make sure that Allergan sales representatives were ready to visit doctor's offices and speak about powerful medications.

199. The emphasis on sales above all else, particularly minimizing training on the compliant and safe way to sell powerful medications like Vraylar, was not limited to Relator's experience. When Relator got to the training session held at Allergan's main office in New Jersey,

one of the sales representatives from a different region was stressed out because he came into the home office training having had only three days to study the materials beforehand. Likewise, on September 28, 2018, Relator spoke on the phone with his Primary Care sales counterpart who told Relator: "My manager told me to sit down in front of the TV and just hit the next button as I was watching TV to get through the modules." This instruction was significant because it came from a different manager than Relator had yet it echoed the same message he had gotten from DM Burrier that the compliance and safety training was less important than sales.

200. On September 28, 2018, Relator had a call with one of the other new hires, Matt Griffin in Sioux Falls, South Dakota. Griffin was out in the field the previous day and admitted to Relator that he gave the wrong adverse event information in a call to a psychiatrist. When the doctor asked him about side effects from Vraylar, Griffin told him the side effects could be diarrhea and nausea. These are the side effects of the other product (Viibryd) that he and Relator would be selling. The potential side effects that he should have said were Akathisia or extrapyramidal symptoms (EPS), two side effects that are much more serious than diarrhea and nausea. Relator and Griffin talked about how unprepared they felt to be out in the field with so little training and the pressure they felt from their manager to be selling despite the lack of training.

201. Later, on November 1, 2018, Relator had another discussion with Griffin, who discussed with Relator his experience with their mutual manager, DM Burrier, stating that Burrier was not concerned about the sales representatives speaking off-label and told him to instead "just be confident in what you are saying."

202. Griffin told Relator about DM Burrier's "confident" off-label marketing. While Griffin was speaking to a physician, DM Burrier took over the conversation and told the physician that he could "just add Vraylar 1.5 mg to the treatment regimen of a patient already on another

atypical drug." DM Burrier went further and told the prescriber that Allergan did not expect him to take the patient off her current medication, because that would be taking a step backwards. Burrier wanted the doctor instead to add Vraylar 1.5 mg and see how the patient feels in one month, saying "then you can decide if you can take away the other atypical." DM Burrier's suggestion was entirely off-label because Vraylar is not indicated for that sort of adjunctive use with other atypical antipsychotics.

203. This coaching from DM Burrier was very common at Allergan when managers were riding in the field with sales representatives. Sales representatives in Relator's district were coached and told that prescribers should just add on Vraylar 1.5mg to whatever current cocktail of medications a patient was on. This sort of widespread adjunctive use of Vraylar is off-label. In fact, the FDA specifically denied Vraylar an indication for adjunctive use of Vraylar for MDD.[101]

204. Relator experienced the lack of emphasis on compliance directly from the training staff as well as the sales managers. On February 21, 2019, Relator had a field trainer with him. When they called on a psychiatrist, the field trainer mentioned Vraylar as an upcoming treatment Bipolar Depression – an indication Vraylar did not have at the time. Although the field trainer brushed this off saying that the Vraylar Bipolar Depression indication would be approved soon, this was not the case at the time of the promotion.

C. Allergan Sales Management's Direction to Use Off-Label Sales Tactics to Promote Vraylar

[101] Nick Taylor, *Allergan and Richter push ahead despite PhIII fail for depression drug*, FierceBiotech (Aug. 8, 2016), https://www.fiercebiotech.com/biotech/allergan-and-richter-push-ahead-despite-phiii-fail-for-depression-drug.

205. Shortly after getting into the field and selling Vraylar, Relator witnessed firsthand the intentional, fraudulent off-label promotion of Vraylar that Allergan's management not just condoned and coached.

206. Upon receiving the approval for the Bipolar Depression indication, Allergan sales representatives were in the field in what was referred to as "pre-launch" mode. During the pre-launch period, Allergan had instructed its sales representatives, including Relator, to call on their top targets and sell the new indication asking for 15-20 patients over the period of two weeks. The pre-launch phase was two weeks before all the sales representatives convened in Hollywood, Florida for the launch meeting and training on Bipolar Depression.

207. After Vraylar received the Bipolar Depression indication in May 2019, Allergan continued (and even increased) its off-label promotion of Vraylar. As alleged above, an indication for Bipolar Depression is different than an indication for Adjunct Depression. Adjunctive treatment of MDD, however, is an indication many Vraylar competitors have, such as Abilify. Thus to compete with these drugs, Allergan decided it would use the new indication to position and promote Vraylar as a direct competitor to drugs with indications that Vraylar did not have.

208. On May 30, 2019, Allergan managers had a conference call with its sales representatives to practice a sales call to make sure they understood the new Vraylar indication for Bipolar Depression and could verbalize the appropriate selling message. Relator was on a call with two other sales representatives (Kevin Markgraf, Charlie Register) and two DMs (Tyler Moriarty, Garrett Burrier) where the three representatives rehearsed the Vraylar sales call and the managers pretended they were the doctors to whom the sales representatives were selling the new indication.

209. During Relator's practice sales call, the managers, pretending to be prescribers Relator was calling on, raised practice physician "objections" to the sales call. For example, at one

point DM Moriarty objected: "When are you [Allergan] getting the Adjunct Depression indication?" Relator handled the question by practicing what he believed was a compliant response: "I do not know. I could fill out a Medical Inquiry Request at the end of this call to get you more information. What I really want to focus on right now is the newest Bipolar Depression indication…." Relator believed this was the legally required and appropriate response to any physician's request for off-label information.

210. At the end of the practice call, the DMs gave feedback on how the sales call had gone. One comment made by DM Moriarty regarded how Relator addressed the inquiry about when Allergan would receive Vraylar approval from the FDA for Adjunct Depression. Moriarty thought that Relator handled the comment "pretty well," but that Relator "should have made the point that the data Allergan was presenting from this Bipolar Depression trial really is the Adjunct Depression data they are looking for," suggesting that the Vraylar data supported off-label use to treat Adjunct Depression. The other manager present, Garrett Burrier (Relator's DM), did not step in and admonish Moriarty that his comment was inappropriate and would be illegal.

211. DM Moriarty's suggestion for Relator's response was clearly off-label. Indeed, it was a direct instruction from a manager to misrepresent the data from a Bipolar Depression trial as data for Adjunct Depression.

212. Later on that same day after the conference call, Relator spoke with another Allergan sales representative who shared his own concerns that they were being asked to engage in illegal conduct. Sales representative Matt Griffin recounted how he had also been on practice sales conference calls with the same managers and had heard some similar feedback from the managers about using Allergan's Bipolar Depression data to sell Vraylar off-label as being effective for Adjunct Depression. Griffin shared his concern with Relator about how different

Allergan is from a compliance standpoint compared to when he had worked at Merck. In comparison to the highly compliant Merck work environment, at Allergan, Griffin said, "it really did not seem to matter what we say or how we sell, as long as we just sell more product."

213. What Relator experienced in the practice sales call was later confirmed in the field. On June 4, 2019, Relator's DM, Garrett Burrier, spent a day in the field with Relator. During that day in the field, Burrier himself promoted Vraylar's new Bipolar Depression indication with health care professionals. Much to Burrier's dismay, the health care professionals they called on were not impressed with the data and Vraylar's new Bipolar Depression indication. In response to this lukewarm response from health care professionals, Burrier instructed Relator at the end of the day that they needed to "blow up the data" and "oversell this data and indication."

214. The next day, on June 5, 2019, Relator talked again with his fellow sales representative, Matt Griffin. That day Burrier in the field with Griffin, again to help promote the new indication and see how health care professionals were reacting. Griffin and Burrier were meeting with an Allergan-trained speaker, key thought leader, and big prescriber of Vraylar, Dr. James Chiu, a psychiatrist from Sioux Falls, South Dakota. Griffin shared with Relator similar troubling directions Burrier had been asking for from Dr. Chiu.

215. During the meeting, Burrier had suggested that Dr. Chiu prescribe Vraylar for all of his depressed patients because "every depressed patient has more going on than just depression." This is clearly an off-label promotion, since Vraylar is only approved for Bipolar Depression and not Adjunct Depression or Major Depressive Disorder.

216. Griffin told Relator how Dr. Chiu had (correctly) given Burrier pushback because Burrier could not equate Bipolar Depression with Adjunct Depression. Griffin related that Burrier was "absolutely" trying to link the two conditions and equate them. Griffin told Relator that Burrier

was "trying to open up the market even bigger. And I think that is what they're doing other places. And that's what maybe we need to do a little bit more. Maybe just say it, I guess just say it, and maybe I will. Maybe I will. But I don't know. Listen, I'm just trying to get the bipolar patients first rather than trying to get everybody at once. And I think that's what Garrett [Burrier] is trying to say is: 'Open it to everybody and then we're going to get to that point.'"

217. Griffin also questioned Relator whether the tactic of expanding the market for Vraylar for use with off-label indications was limited to just their region. When Relator asked if the scheme to sell Vraylar for unapproved uses was bigger than just their region (*i.e.*, a national issue) or limited to just their region, Griffin responded:

> I think it's both. … I think it is Garrett's way of building a bigger market, a bigger potential convincing them that it can be used for any type of patient, anywhere, whether it is adjunct or not. … But I think it's more Garrett saying, "hey, if we're doing 50% reduction, we're going to work for every type patient that's depressed. Regardless of if they are bipolar or not."

218. Later that day on June 5, Griffin told Relator that Dr. Chiu called Burrier to apologize for not having more time to talk earlier in the day. Griffin overheard the call and on it Burrier told Dr. Chiu how he could get Vraylar covered for the off-label use to treat Adjunct Depression. Burrier explained this could be done by having specific patients with commercial insurance use a Vraylar co-pay card and having pharmacists bypass insurance using an "03 Other code" when the prescription is being processed. When a pharmacist does this, the insurance is overridden and patients usually pay no more than $75 for the prescription. Allergan essentially acts as the insurer and gets a portion of the $75.

219. On June 25, 2019, Relator was on a district-wide conference call. DM Burrier and RM Cox were both on the call and guiding the off-label promotion of Vraylar for generalized depression, a much bigger and broader market than Vraylar's actual indication. As Burrier

explained, the sales message for Vraylar should be beyond its limited indications to encompass depression – not Vraylar's more limited indication for Bipolar Depression. Burrier made clear they were to be selling the drug well beyond its limited Bipolar Depression indication:

> So with just the depression component of our message, because we've been three years where we've talked about depression and they're irritable and they're agitated and things like that. We've got to get away from the irritability, the agitation. It's just straight up depression. That's what they're dealing with. Because it's not mixed anymore. It's not manic. It's just straight up depression, and in some point in time, they had something else.

220. Even in the face of questions from a sales representative who thought that the strategy of going after depressed patients did "not make a lot of sense," Burrier did not relent in the off-label message. He told them: "At some point in time a mixed patient, Bipolar Depression is just depressed. They don't have any mania going on at that point in time."

221. Another Allergan sales representative and former manager, Damian Stednitz, seconded the off-label promotion for depression: "So it's getting them to think differently about the product. Keep mentioning 'depression, depression, depression' till they get it thinking in their head." Burrier repeated the recommendation that selling for depression – not Bipolar Depression – is "a great point."

222. DM Burrier further expanded on the off-label promotion for depression to make sure that the sales team is "dialed into the depression for these patients," remarking that some of the sales representatives "might have already been doing this." Burrier was concerned that selling Vraylar only for its approved indication (*i.e.,* mentioning mixed depressive symptoms for Bipolar Depression) will turn off providers and have them refuse to prescribe Vraylar. Instead, Burrier instructed the sales representatives to ask the doctors to look at their schedules to see how many patients are suffering from depression alone because that total will likely be a very high percentage

of the doctor's patients, likely 80-90%. Burrier directed them to target those patients for Vraylar use.

223. RM Cox was on the same call. Cox not only supported the off-label instructions from the DM Burrier, but also explicitly doubled down on the sales representatives selling off-label. Cox explained his interaction with 20 to 30 Vraylar speakers who supported selling well beyond its limited Bipolar Depression indication:

> I asked probably 20 or 30 doctors that were at the speaker training this weekend: "How would you sell this?" Their answer was the exact same. They said as an antidepressant. It's just the data, the data's as good as any antidepressant out there. Obviously they know it's indicated for Bipolar, but they were like, "you've just got to get the doctor to think about depression not... because they're not going to touch mania, particularly in primary care or even any part of that." So I think you guys are dead on. It has to sound different than it has over the past couple of months.

224. Even when a sales representative raised a concern that selling Vraylar for depression meant that they would be "talking off-label" and "could get [the Allergan sales representatives] into some trouble," this point was completely dismissed by the sales managers. DM Burrier incorrectly told Relator and other sales representatives on the call that Bipolar Depression and depression are the same thing, so selling for depression is approved. He stated: "So you're on label 100 percent when you tie it into their depressed [patients]. That's all they are, but at some point in time they've had this go on that makes them a bipolar depressed patient."

225. Another sales representative, Ashley Hadden, chimed in saying that Vraylar should be used for non-indicated depression as well: "Don't get overcomplicated by this MDD [major depressive disorder] versus Bipolar Depression. Like, do they have depressive symptoms and do they want them resolved? Take care of it."

226. Sales representative Warren Valenta summed up the sentiment bluntly: "If they like Vraylar, we need to say: 'Hey, that's great, but I want you to replace that with depression. I want depression to be your number one usage for Vraylar.'"

227. After the conference call, Relator spoke with three district sales representatives: Matt Munson, Julie Miller, and Matt Griffin. All of them were very surprised about how out in the open the off-label discussion had been on the regional call and, in particular, that the discussion was being guided by their DM and RM. Clearly, it was not just Relator who concluded that Allergan was directing them to promote Vraylar off-label for all depressed patients when talking to psychiatrists and PCPs.

228. In a conversation Relator had with Matt Munson, another sales representative, Munson remarked that DM Burrier had always been one to "push the boundaries" and that "off-label is kind of a big thing, but [Burrier's] always pushing the boundaries with stuff." Munson concluded that the fact that DMs talking to a large group of sales representatives to push the boundaries was an invitation for the sales representatives to promote Vraylar for off-label uses.

229. Relator had another long conversation with Julie Miller after the district conference call. Miller had spoken up on the district call raising concerns that the instructions from management sounded like promoting off-label. When Relator talked to her privately over the phone after the district call, she could not believe what the sales representatives were being told to do. Miller felt that what was said on the call was clearly off-label promotion of Vraylar for all depressed patients (even those without a history or discussion of manic symptoms). In fact, she was disturbed at the brazenness of the call with RM Cox approving of and helping guide Allergan's messaging. When Relator asked her why the message on the regional call was seemingly different than the messaging they had heard at the National Meetings (which had been by-the-book),

Miller's belief was that the messaging at National Meetings was different because somebody from Compliance was likely in their breakout room.

230. On July 1, 2019, there was a call with about fifteen Specialty and Primary Care sales representatives from the region as well as three DMs, Garrett Burrier, Tyler Moriarity and Anna Koraleski, who listened in and added their commentary. The call was moderated by sales representative Ashley Hadden, who was enrolled in a leadership development program to groom future DMs and was sharing ideas with the sales team from that program.

231. Hadden went through the process for selling doctors on Vraylar's use for all forms of depression, essentially a "how-to" for off-label promotion. By using the sales aids, Hadden explained how she sells symptoms, expanding the potential uses of Vraylar beyond those for which it is indicated:

> I've been starting the page with the three graphs that shows the MADRS drop. The reason I've done that is because I've been launching to a lot of PCPs, and that page doesn't say anything about mania or mixed. So it feels like an easier entry point for me on that page, because they don't see [Bipolar Depression].... That windshield page I love, but I like to go to it second, after we've gotten established that we're talking about depression, because I think they see that windshield page and it's the first thing they see is mania and mixed at the top. Their eyes go straight to it. So I like to do that second and go in that order, just to ease them into the bipolar scary word, if that makes sense. But those are the two first.

232. On an August 13, 2019 call, Relator's DM Burrier again talked through sales strategy. Once again Burrier referred to Vraylar being useful for the depressed patient, making no distinction between the indicated use of Vraylar for Bipolar Depression and MDD, a non-indicated but much more common use. Burrier encouraged the sales representatives to check in after they call on a doctor and said that the sales representative should ask: "Doc, it makes sense, but I know you haven't really gravitated towards that depressed patient where you've probably used those

medications in the past or when you see those patients that aren't symptom-free. I know not every one of those are getting Vraylar, but how do we move towards that where at least the everyday."

233. On the call Burrier also directed the sales representatives to insist that prescribers start 15 to 20 patients on Vraylar in the next two weeks – regardless of whether there is that number of patients with approved indications. Burrier told the representatives to sell to a sales number, not the label. He said: "Are we consistently asking for that quantity of patients and super confident in what we're asking for. It doesn't sound like a lot. When we waffle. And I hear people be like, Oh, there's probably a few, and we're not real confident. It doesn't sound like, when I listened to it, it doesn't sound like it's even doable. But like today, Warren [Valenta] was so confident in 15 to 20 patients, it almost seemed like he was underselling the drug because it was so matter of fact."

234. On August 23, 2019, Relator had a phone call with Ashley Hadden, another sales representative in the district. The call was to get feedback on how she was successfully selling Viibryd, but the call also talked about selling Vraylar.

235. On the call Hadden continually blurred the lines when talking about her selling practices. She never discussed on her sales calls the use of screening tools, DSM criteria or indications. Rather, at one point she described her tactics as "trying to keep it as simple as possible for folks, especially because we are putting such a heavy focus on depression with Vraylar." To Relator, Hadden intentionally used the term "Depression," not "Bipolar Depression," and indication Vraylar did not have.

236. Hadden went on to talk about selling for the appropriate Vraylar patient based on the patient's symptoms and against Abilify. She said she tells prescribers: "If you start looking at any Abilify patient that comes in that's not symptom free or that's dealing with the side effects,

that has to be a Vraylar patient and that's how you're going to grow." Yet Abilify and Vraylar do not have the same indications – something Hadden did not seem to mind.

237. Hadden also admitted that she has been selling Viibyrd and Vraylar to prescribers as a way to get patients to "remission" for depression. This is certainly something that is not an approved use for either drug, and for which there is scant clinical evidence. As Hadden puts it:

> I've used it with Vraylar, too. It's just trying to paint the picture of how often they have the opportunity to use it. "Do you see depression every day?" And if they say "yes," I ask: "How often are patients on their first anti-depressant coming in and actually getting to remission on that anti-depressant?" And now the answers across the board are like, "Oh gosh, maybe half." Okay. So 50% of the time when he started the anti-depressants, that patient's going to come back and they're not to remission. That's exactly where you have to use Viibryd and that's why I'm asking you to use more.

238. On September 18, 2019, Relator had a check in call with his DM Burrier. Burrier had just been at a manager's meeting and was following up with representatives in the district to discuss how things were going in the field using their selling strategies.

239. The call eventually turned to the off-label promotion of Vraylar. Burrier encouraged the promotion of Vraylar to doctors for patients who are stable and not exhibiting any signs of Bipolar Depression, much less any manic/mixed episodes. He said: "Don't think it's something you bring out every call, but I think when you get pushback, like: 'Yeah, all my patients have been stable.' I tell them, like, 'Doc, I get it. Even when you look at the study here, 50% of the time, when they looked at this long-term, patients were asymptomatic. But I think there's a couple different ways. I think for primary care it doesn't matter as much for you. You can tell a story with primary care about that. I get why it's so hard to diagnose. Think about how much of these [patients]... it might be asymptomatic from the standpoint of no feeling. Not like they're

depressed, they're just numb.'" Burrier stressed to Relator the uses of Vraylar for patients who are "just numb" and are "asymptomatic."

240. What Burrier continued on to say is that Vraylar should be used until the patient is completely symptom-free. Here's the exchange between Relator and Burrier:

> *Burrier*: That doesn't mean they're hitting every parameter to be considered Major Depressive Disorder. That's basically what it's saying is 53% of the time, or whatever the numbers were, they don't meet the criteria to be clinically depressed. That's probably a patient you might consider stable that still has some residing symptoms. So when they're looking at that 53%, that's what they're looking at. Like, at any given point in time, they are not meeting the criteria of Major Depressive Disorder. So they're better. What you're saying is right. They no longer meet the criteria.
>
> *Relator*: Right.
>
> *Burrier*: But they're still not symptom-free. And to me, that's probably the bigger part of the story. It's almost validating. Clinically, at the point in time they're not considered Major Depressive Disorder. But there's still some underlying symptoms that they're also not symptom-free.

241. When Relator remarked on the difficulty of selling Vraylar because prescribers have pigeon-holed it for the mixed/manic patient, Burrier directed Relator to sell instead for plain depression, telling him:

> Everybody is just hammering right now, 'depression.' Does it stick with people? Not all the time. But, that example Damien sent a couple weeks I thought was right on. There was two or three more examples from managers that were very similar to that….. But if you boil it down, just from those people that are just using the hell out of it and using it for depression, and probably using it for some Adjunct Depression, as well, that's where we know we're on the right path with some of these folks. They're really seeing it as a potent antidepressant that's different, that's able to treat this disease state unlike any other medication, where you're getting these drops without an antidepressant on board, without a mood stabilizer on board, with these folks. Because at the end of the day, let's be honest, a lot of these patients are going to be on one or the other of those meds.

242. Burrier also described the sales tactic of simply substituting Vraylar for other competitor drugs with entirely different indications. He suggested asking doctors: "I'm just going

to ask any patient on Abilify or Latuda that can do better, that you give Vraylar a shot, or any patient where you'd use that, you give Vraylar a shot, and here's why." Of course, the problem with Burrier's instruction is that Abilify and Latuda do not have the same indications as Vraylar and thus cannot be compared in one-to-one substitutions.

D. Allergan Targeted Off-Label Prescribers of Vraylar, Using Intentionally Misleading Claims Regarding Depressive Symptoms to Promote Vraylar

243. One of the main areas where Allergan has promoted Vraylar off-label has been its attempt to sell and expand the use of Vraylar to Primary Care Physicians (PCPs). This is problematic because PCPs generally do not treat either Bipolar Disorder or Schizophrenia – the only FDA-approved indications Vraylar had before June 2019. Nor do PCPs generally treat Bipolar Depression, the indication Vraylar received at that time. Instead, they almost universally refer these patients to psychiatrists and other specialists.

244. Allergan made no effort to ensure that its Target Call Panels contained prescribers who would be writing on-label. Relator's call panels often contained prescribers who it knew would very likely not be writing Vraylar on-label.

245. To increase Vraylar sales for off-label uses to treat MDD, Allergan made a concerted push to sell Vraylar to PCPs. Relator was told in a sales meeting that as much as 25% of the atypical antipsychotic business at some of Allergan's competitors like Sunovion Pharmaceuticals Inc. (maker of Latuda) and Bristol-Myers Squibb (maker of Abilify) comes from PCPs. By contrast, Vraylar's market share from PCPs was only about 12% nationally. Thus, Allergan managers directed sales representative they were to increase sales of Vraylar to PCPs.[102]

[102] While Relator, and most other CNS Specialty sales representatives, had PCPs on their call panels, the CSR sales team, who also promoted Vraylar, primarily called on PCPs.

246. Allergan's plan to sell to PCPs was difficult to reconcile given Vraylar's limited indications. Simply put, few PCPs have widespread need for a drug like Vraylar especially given the wider indications of other atypical antipsychotics. For example, Abilify is indicated for adjunctive treatment of MDD. Yet, Allergan persisted in its goal to increase its market share amongst PCPs. To do so, Allergan decided to downplay Vraylar's approved uses, and instead promote Vraylar off-label.

247. The targeting of PCPs is clear from the call panels that Allergan provided its sales representatives. Every quarter, Allergan sales representatives get "Target Call Panels" of prescribers on whom they are supposed to call. The list is divided into A Targets and B Targets. The A targets are considered the high priority/high potential targets and sales representatives are expected to be calling on them more often than B targets.

248. Relator's manager insisted the sales representatives to visit all of their A Targets. On April 12, 2019, DM Burrier texted numerous sales representatives: "Team, slow down this morning and take inventory on how many A targets you've seen this week that you didn't see last week. What A targets did you not see this week because of one reason or another you need to get in front of today."

249. To increase the chance of successful off-label promotion to PCPs, Allergan sales management coached sales representatives they were never to use the word "bipolar" when selling Vraylar to PCPs. They did this because they believed that PCPs would be turned off and unreceptive to hearing about a medication when the word "bipolar" is used, because it is a condition PCPs do not treat and instead refer to psychiatrists.

250. Instead, Allergan sales managers coached sales representatives to refer to use the terms "mood disorders," "mood instability," or "depressive patients." All of these terms were

intended to sound more acceptable to PCPs and were to hide the fact that Vraylar is only indicated for Bipolar Depression. This was a very intentional choice by Allergan because, while PCPs generally *do not* treat Bipolar Disorder, PCPs often *do* treat depression. So by marketing Vraylar to treat mood disorders, Allergan was deceptively promoting Vraylar off-label PCPs.

251. Even though the Allergan Primary Care Sales Aid summarized the DSM criteria for mixed/manic features, Allergan sales management told sales representatives not to talk about the requirement to screen for mania before prescribing Vraylar. This blatantly ignored the fact that, to be diagnosed with Bipolar I Disorder as defined in the DSM-IV or DSM-5 criteria, a patient needs to have a history of manic episodes, typically lasting for one week or more.

252. Likewise, as part of its illegal scheme, Allergan's off-label promotion of Vraylar centered largely on selling the symptoms of Bipolar Depression and not the disease state itself. In doing so, Allergan misleadingly promoted Vraylar's demonstrated safety and effectiveness in reducing symptoms of Bipolar Depression as evidence of Vraylar's safety and effectiveness for treating off-label MDD because it shared similar symptoms. Without the mania in addition to the depression, Vraylar use would be off-label – a distinction about which Allergan intentionally misled prescribers.

253. For example, after the FDA approved the expanded use of Vraylar in the treatment of Bipolar Depression on May 27, 2019, Allergan trained sales representatives, including Relator, to promote Vraylar's safety and effectiveness for treatment of depressive symptoms associated with Bipolar Disorder as evidence of Vraylar's safety and effectiveness for treatment of depressive symptoms generally and MDD specifically, regardless of the fact that neither are associated with Bipolar Disorder.

254. In this manner, by deceptively focusing its promotion on symptoms while deflecting health care professionals' attention from Vraylar's limited FDA-approved indications, Allergan made sure its sales representatives leveraged visual sales aids that were facially approved to promote Vraylar for off-label uses. Allergan thus obscured the reality of its sales representatives' promotions by maintaining the façade that their promotions were approved, even as sales representatives used the sales aids as supplements to their promotions of Vraylar for off-label uses.

255. For example, on February 25, 2019, Relator was in the field with his manager, DM Burrier. Before calling on new primary care providers (Kayla Bower, FNP and Gregg Rapp, PA of Stevens Community Medical Center located at 501 Poler St., Starbuck, Minnesota 56381), DM Burrier reviewed with Relator the importance of not using the word "bipolar" because it would immediately kill the chance of any sale. As was the practice, Burrier instructed Relator to use the term "mood disorders" instead. Burrier also suggested that Relator should not talk about what the indicated uses were for Vraylar, but rather talk about different symptoms the physician may see in a patient (elevation, agitation, irritability) that Vraylar could help manage even if those symptoms were connected with an off-label indication.

256. The illegal marketing of Vraylar to Bower and Rapp is underscored by the fact that both health care professionals' practices include caring for pediatric patients. Bower says that she "has a particular passion for preventive medicine and thoroughly enjoys working with teenagers and young adults.[103] Likewise, Rapp says that he "enjoys the full scope of family practice including

[103] Kayla Bowers, Stevens Community Medical Center, https://www.scmcinc.org/staff/providers/kayla-bowers-aprn-fnp-c.

pediatrics."[104] Besides being PCPs, both prescribers focus their practice on the treatment of children with whom the use of Vraylar is not only not proven effective, but potentially extremely dangerous. Even so, Allergan intentionally marketed Vraylar off-label to these health care professionals.

257. In another example, during regional sales sessions at a June 17-20, 2019 national sales training for selling the new Bipolar Depression indication, three DMs and the RM gave explicit directives on how to sell the new Bipolar Depression indication to PCPs. The messaging and strategy outlined in these meetings was very different than what is outlined in the corporate marketing materials.

258. Illustrating its veneer of compliance, when Allergan thought that the sales representatives were not being monitored, such as during role play exercises at district sales meetings, sales representatives were coached to rehearse before their managers using illegal off-label promotional messages that Vraylar was safe and effective for the treatment of a litany of off-label uses, including MDD.

259. When one sales representative was practicing his selling message in front of the group of managers and other representatives, the representative used the word "bipolar" when promoting Vraylar in the scenario. After the role play, feedback was given by another representative (Warren Valenta) that the representative should have used the term "mood instability" instead of "bipolar" because he was talking with a PCP. All four managers agreed and stressed the importance of this strategy.

[104] Gregg Rapp, Stevens Community Medical Center, https://www.scmcinc.org/staff/providers/greg-rapp-pa-c.

260. On June 24, 2019, Relator spoke to his manager Burrier on the phone about selling to PCPs. On the call, Burrier explicitly expressed his desire that his sales representatives be out in the field selling to PCPs: "[I]t would be nice to have him out there, being able to call in primary care with Bipolar Depression methods." Yet Burrier recognized that primary care was not the proper setting for Vraylar: "You've got to be a wordsmith to be able to sell [Vraylar for] manic and mix[ed patients] in a primary care setting."

261. Yet, later in the conversation Burrier set aside any pretense about being a "wordsmith" and just told Relator to promote Vraylar for Depression, stating: "It's just, they're depressed. That's it. They have no other symptomology going on right now, other than depression. That's it."

262. Allergan sales managers consistently instructed sales representatives to sell Vraylar to PCPs as appropriate if a patient has tried and failed on two to three antidepressants, with the sales representatives suggesting that the patient may not have depression alone and could benefit from a trial of Vraylar. The condition "Bipolar Disorder" was never to be mentioned.

263. Another common scenario pushed by Allergan sales representatives was to suggest Vraylar for a patient who is not responding to an antidepressant and had any of the vague symptoms outlined in the Vraylar sales aid (*e.g.*, "excess energy," "racing thoughts," "family history," etc.). Again, the condition "Bipolar Disorder" and the fact that Vraylar is an antipsychotic drug were not to be brought up since this terminology would scare off these PCPs from prescribing.

264. In furtherance of the off-label scheme to sell to prescribers who may not be interested in using Vraylar for its accepted indications, Relator's RM, Josh Cox, gave clear directions to Relator's sales group for calling on PCPs. For example, Relator witnessed and made note of Cox making the following deliberately misleading and deceptive instructions:

- "Don't make it complicated in asking them to use Vraylar. They don't need to screen (by using DSM criteria) every patient."
- "Primary care physicians know who these patients are that don't respond to an SSRI. The goal is not to screen every patient, but have them use their own logic."
- "Ask the doctor if they have used five antidepressants this week. If they answer yes, then they have seen a patient with Bipolar, because 1 in 4 patients on an SSRI is misdiagnosed with depression that actually has Bipolar Disorder."
- "If a Primary Care physician is using Lamictal for depression, they could be using Vraylar instead."

265. Allergan put patient health and safety at risk by intentionally misleading prescribers to believe that Vraylar has broader indications than it does. This sort of illegal, off-label promotion leads to prescribers who are largely unfamiliar with extremely powerful medications like Vraylar (such as PCPs) using Vraylar for patients that could be treated with less risky (and cheaper) alternatives.

E. Allergan's Call Panels Target Sales to Physicians Who Do Not Use Vraylar On Label

1. Allergan Targeted Its Deceptive Off-Label Scheme to Health Care Professionals Who Treat Only or Predominantly Children and Adolescents

266. Allergan also consistently targeted child and adolescent PCPs for the off-label use of Vraylar. Relator's Target Call Panel contained 127 A targets. Of that list, at least 11 (nearly 10%) were PCP's that see primarily (if not solely) children and adolescents. Vraylar is not indicated for use in adolescents or children.

267. Off-label use of atypical antipsychotics among children and adolescents has exploded despite the lack of research into their safety and effectiveness for these uses and in this population. Dr. Ronald Brown, who headed an American Psychiatric Association committee that

evaluated the issue, put it succinctly: "The bottom line is that the use of psychiatric medications far exceeds the evidence of safety and effectiveness."

268. The Chairman of the DSM-IV Task Force, Dr. Allen Frances, attributed the excessive prescribing of antipsychotics for pediatric use to the influence of drug manufacturer promotion, writing that "[w]hen the adult market [in psychotropic drugs] seemed saturated, the drug companies expanded their customer demographics by pushing product onto children—it is not by accident that all the recent epidemics of psychiatric disorder have occurred in kids. And children are particularly choice customers—bring them on board early, and you may have them for life."

269. The brunt of this questionable prescribing is disproportionately borne by lower-income children. Federally funded research revealed a stark disparity: children covered by Medicaid are prescribed antipsychotics at a rate four times higher than children covered by private insurance.[105] Moreover, Medicaid-covered children are more likely to receive the drugs for less-severe conditions than their middle class counterparts, the data showed.

270. Vraylar's label plainly states the risks associated with use of antidepressants for children and adolescents:

> In pooled analyses of placebo-controlled trials of antidepressant drugs (SSRIs and other antidepressant classes) that included approximately 77,000 adult patients and 4,500 pediatric patients, the incidence of suicidal thoughts and behaviors in antidepressant-treated patients age 24 years and younger was greater than in placebo-treated patients. There was considerable variation in risk of suicidal thoughts and behaviors among drugs, but there was an increased risk identified in young patients for most drugs studied. There were differences in absolute risk of suicidal thoughts and behaviors across the different indications, with the highest incidence in patients with MDD.

[105] Duff Wilson, *Poor Children Likelier to Get Antipsychotics*, N.Y. Times, Dec. 9, 2009, *available at* http://www.nytimes.com.

271. Despite the clear dangers of prescribing Vraylar off-label to children and adolescents, Relator's A Target Panel included numerous PCPs who saw primarily or exclusively children and adolescents. These prescribers included:

- Patricia Blummenreich, MD from First Street Center located at 540 E 1st St, Waconia, Minnesota, 55387. Dr. Blummenreich practices "General pediatric psychiatry" and sees "children age 5-18."
- Barry Garfinkel, MD, from the Center for Developmental Pharmacology located at 3033 Excelsior Blvd, Suite 210, Minneapolis, Minnesota 55416. His practice involves "Child & Adolescent Psychiatry."
- Elysia Peterson, NP from Shifting Focus, PLLC, located at 408 Great Oak Drive #408A, Waite Park, Minnesota 56387. In addition to Shifting Focus's Facebook page clearing indicating in its very large logo at the top of the page that its focus is "Child & Adolescent Behavioral Health,"[106] Peterson's description of her practice underscores the point. Peterson "offers psychiatric evaluation, treatment, and medication management for children ages 3-21" and lists her specialties as Autism Spectrum Disorders, Fetal Alcohol Spectrum Disorders, and trauma – none of which are indicated uses of Vraylar.
- John Luehr, MD, from Sonder Behavioral Health & Wellness located at 12301 Whitewater Drive, Suite 101, Minnetonka, Minnesota 55343. Dr. Luehr who lists as

[106] Shifting Focus PLLC: Child & Adolescent Behavioral Health, FACEBOOK (February 24, 2020), https://www.facebook.com/pages/category/Mental-Health-Service/Shifting-Focus-PLLC-103081957700466/.

patient focus "Children (6 to 10), Preteens / Tweens (11 to 13), and Adolescents / Teenagers (14 to 19)".[107]

- LeAnne Rohlf, CNP from Nystrom & Associates, located at 900 Silver Lake Road Suite 110 Minneapolis, Minnesota 55112. Nystrom & Associates' webpage makes it abundantly clear that Rohlf's practice involves exclusively child and adolescent care. It states that Rohlf enjoys "working with children and their parents as a team reaching a common goal- helping the child and their family to be healthy and successful"; it lists her clinical interests as "working with children, adolescents, and young adults."; and it lists her "Behavioral Health Certifications" as Pediatric Nurse Practitioner (PNP), Psychiatric Mental Health Nurse Pracitioner (PMHNP), and Pediatric Mental Health Specialist (PMHS).[108]
- Patti Brown, CNS from Nystrom & Associates located at 13603 80th Circle North Maple Grove, Minnesota 55369. Brown "especially enjoy[s] working with teens and young adults."
- Kim Holtmeler, MD from BHSI located at 8441 Wayzata Blvd, Suite 140, Golden Valley, Minnesota 55426. Dr. Holtmeler provides "diagnostic evaluations and medication management for children, teens, and young adults."

272. All of the examples above show how Allergan intentionally targeted prescribers that treated primarily, if not exclusively, children and adolescents. Even if the prescribers did treat a small number of adults, the combination of the off-label messages about Vraylar's use for

[107] John G. Luehr, Psychology Today, https://www.psychologytoday.com/us/psychiatrists/john-g-luehr-minnetonka-mn/412888.
[108] LeAnne Rohlf, Nystom & Associates, https://www.nystromcounseling.com/our-providers/leanne-rohlf/.

depression (not its indicated use of Bipolar Depression) with Allergan's knowledge of the prescriber's treatment of children/adolescents make the marketing to these prescribers off-label and illegal.

2. Allergan Targeted Other Physicians with Its Deceptive Off Label Scheme

273. Relator's A Target Panel also contained at least three neurologists, who do not use Vraylar for the treatment of any on-label conditions. These neurologists included:

- Jonathan Calkwood, MD from the Minneapolis Clinic of Neurology, located at 4225 Golden Valley Road, Golden Valley, Minnesota 55422. Dr. Calkwood specializes in the treatment of multiple sclerosis and neuro-ophthalmology.
- Robert Jacoby, MD from the Noran Neuroglogical Clinic, located at 2828 Chicago Ave, Suite 200, Minneapolis, Minnesota 55407. Dr. Jacoby's care and clinical interests are dystonia, headache, multiple sclerosis, Parkinson's, tremor.
- Moeen Masood, MD from the Minneapolis Clinic of Neurology, located at 3833 Coon Rapids Boulevard, Suite 100. Coon Rapids, Minnesota 55433. Dr. Masood specializes in neuromuscular diseases and neurological rehabilitation.

274. Neurologists are inappropriate to have on a call panel for Vraylar because neurologists do not treat patients suffering from any of its approved uses and the vast majority of their use of atypicals and antidepressants would thus be off-label. When Relator asked DM Burrier why neurologists are on their call panels, Burrier replied that it was because "neurologists write atypicals all the time."

275. Further proof of Allergan's call panels being ripe for off-label targeting is evidenced by the presence of an orthopedic specialist (Hans Backlund, PA-C from St. Cloud

Orthopedics in Minnesota) on Relator's call panel as an A Target. There is no reason why an orthopedist would be using Vraylar on label, and in fact the orthopedic doctor on the call panel had only prescribed Vraylar once. Yet, Allergan sees "a sale as a sale" and keeps all types of doctors on its call panels even if they are assuredly not writing Vraylar for approved uses.

F. Use of Vraylar Free Samples to Facilitate Off-Label Promotion for the Treatment of MDD Patients

276. As part of its off-label promotion of Vraylar, Allegan provided its sales force with large volumes of samples of Vraylar designed to promote off-label use of the drug.

277. Sales representatives get a monthly allocation of samples. There is an upper limit to the typical allotment of 5 cases of Viibryd and 3 cases of Vraylar, with 72 pills per case. It was easy for sales representatives to get more samples – all they had to do was ask their manager. Relator did this on a regular basis, getting several additional cases per month. There is no limit on how many samples a sales representative is allowed to leave with any one prescriber.

278. Allergan knew that its provision of product samples effectively influenced health care professionals to prescribe Vraylar. Many health care professionals on whom Relator called relied on product samples to initiate new patients on antidepressant or antipsychotic therapy, and those health care professionals would not have routinely prescribed Vraylar but for their receipt of product samples from Allergan. Samples of Vraylar therefore caused health care professionals to increase the amount of Vraylar that they prescribed.

1. Allergan Provided Vraylar Samples to Health Care Professionals It Knew Would Use Them for Off-Label Uses

279. Allergan also knew that its provision of Vraylar product samples to health care professionals who did not treat patients for its approved uses, or to health care professionals whom

Allergan had promoted those drugs for off-label uses, influenced those health care professionals to prescribe Vraylar for off-label uses.

280. While health care professionals' provision of Vraylar product samples to their patients did not in itself result in the submission of any claims, the samples caused health care professionals to provide their patients with prescriptions for continuing therapy on Vraylar when subsequent prescriptions were filled by pharmacies and caused the submission of false claims to Government Programs, as alleged *infra*. Allergan knew and intended that its provision of samples would cause the submission of claims resulting from prescriptions for continuing therapy in this manner.

281. Allergan's malfeasance and disregard for the law extended beyond sampling for prescribers who write off-label. On April, 23, 2019, Relator spoke with one of the new hires with whom he went through training and the other sales representative told Relator of a sampling issue he encountered. Shortly after the sales representative started, he oversampled a clinic by entering in the wrong quantity. He called DM Burrier for guidance on what to do. Instead of having the sales representative call the Sample Compliance Department, DM Burrier told him to correct the quantity by under sampling a different office to offset the mistake. He told him to do this in a larger office that would not know the difference.

2. Allergan Provided Samples to Health Care Professionals Treating Only or Predominantly Children and Adolescents It Knew Do Not Use Vraylar On Label

282. Likewise, Allergan used is Vraylar samples to leverage off-label uses by child and adolescent health care professionals.

283. From only a cursory review, Relator was able to identify numerous examples of health care professionals who primarily (or exclusively) treat children or adolescents as targets on

call lists and to whom Allergan sales representatives were allowed to provide free samples of Vraylar.

284. For example, Allergan allowed sampling to prescribers like Connie Semmelroth, a Child and Adolescent NP from Nystrom & Associates, in Minneapolis, Minnesota. Semmelroth's profile clearly states that she is "interested in the treatment/assessment of child/adolescent for behavioral health."[109] Also, the sales notes for Semmelroth explain that she wants to use Vraylar more with "depressive symptoms." Yet, Allegan allowed sales representatives to sample her with Vraylar as is indicated by the "OK to Sample" box being checked in her profile in Allergan's sales system. Thus, Allergan is not only targeting, but also allowing sampling, a prescriber who deals with children/adolescents (an off-label use of Vraylar) and one that is looking to use Vraylar for depression (an off-label use of Vraylar).

285. Semmelroth is not alone. Michael Adelman, MD from Nystrom & Associates located at 1900 Silver Lake Road, Suite 110 Minneapolis, Minnesota 55112 is clearly identified as a child psychiatrist. His clinical interests are "Child and Adolescent Psychiatry" and he is interested in applying "a broad biophysical approach in [his] work with children and families…." Yet, Allergan considers Dr. Adelman "ok to sample" with Vraylar.

286. Likewise, Nicole Larson, CNP from Nystrom & Associates located at 4300 West 147th Street Suite 204 Apple Valley, MN 55124 treats children. Her clinical interests are "Pediatrics: Depression, Anxiety, OCD, Bipolar Disorder, and ADHD." Yet, Allergan listed her as someone "ok to sample."

[109] Connie Semmelroth, Nystrom & Associates, https://www.nystromcounseling.com/our-providers/connie-semmelroth/.

287. Other examples of prescribers who treat primarily or exclusively children and adolescents that were considered "ok to sample" by Allergan are:

a. Amanda Johnson-Fleming, from Nystrom & Associates, located in Eden Prairie, Minnesota who is listed as a "Pediatric Nurse Practitioner" and has her clinical interests as "Depression, anxiety, ADHD, PTSD, ODD, and FASD." She also notes that she has "3 years of pediatric mental/behavioral health RN experience."

b. Emunah Rankin, DNP from Nystrom & Associates, located 1900 Silver Lake Road, Suite 110 Minneapolis, Minnesota 55112. Rankin's "Clinical Interests" are "Child and Adolescent Mental Health" and her clinical approach is to "approach each child or adolescent as a whole person in the context of a family system."[110]

c. John Glass, MD from Nystrom & Associates, located 1900 Silver Lake Road, Suite 110 Minneapolis, Minnesota 55112. Glass's "Clinical Interests" are "General child and adolescent psychiatry."[111]

d. Kendra Kruger, PA from Nystrom & Associates, located 9245 Quantrelle Ave Ne Otsego, Minnesota 55330-0168. Kruger's "Clinical interests include child and adolescent health promotion, anxiety, depression, ADHD, PTSD, and OCD, but see many kids for many different reasons as well."

e. LeAnne Rohlf, CNP from Nystrom & Associates, located at 900 Silver Lake Road Suite 110 Minneapolis, Minnesota 55112. Nystrom & Associates'

[110] Emunah Rankin, Nystrom & Associates, https://www.nystromcounseling.com/our-providers/emunah-rankin/.
[111] John Glass, Nystrom & Associates, https://www.nystromcounseling.com/our-providers/john-glass/.

webpage makes it abundantly clear that Rohlf's practice involves exclusively child and adolescent care. It states that Rohlf enjoys "working with children and their parents as a team reaching a common goal- helping the child and their family to be healthy and successful"; it lists her clinical interests as "working with children, adolescents, and young adults."; and it lists her "Behavioral Health Certifications" as Pediatric Nurse Practitioner (PNP), Psychiatric Mental Health Nurse Pracitioner (PMHNP), and Pediatric Mental Health Specialist (PMHS).[112]

f. Rachel State, MD, from Nystrom & Associates, located at 900 Silver Lake Road Suite 110 Minneapolis, Minnesota 55112. State specializes in "outpatient treatment and management of mood, anxiety, behavioral, and psychotic disorders in children and adolescents." State also is Board Certified in Child & Adolescent Psychiatry and is Board Eligible in General Pediatrics.[113]

a. Sarah Myer, PNP from Nystrom & Associates, located at 817 N, Main St NE, Cambridge, Minnesota 55008. Myer's clinical interests are Pediatric and adolescent mental health. She also holds Behavioral Health Certifications as a pediatric nurse practitioner and pediatric mental health specialist.[114]

288. Simply put, there was nothing Allergan did to stop its sales representatives from sampling powerful medications to health care professionals it knew would likely use the samples off-label, especially with children.

[112] LeAnne Rohlf, Nystrom & Associates, https://www.nystromcounseling.com/our-providers/leanne-rohlf/.
[113] Rachel State, Nystrom & Associates, https://www.nystromcounseling.com/our-providers/rachel-state/.
[114] Sarah Myer, Nystrom & Associates, https://www.nystromcounseling.com/our-providers/sarah-myer/.

289. Despite the risks of off-label use of Vraylar in children and adolescents, off-label sampling of Vraylar for the treatment of children is common and illegal.

G. Call Notes Demonstrate Allergan's Off-Label Promotional Strategy Was Designed to Sell Vraylar as a Replacement for Differently Indicated Drugs

290. The off-label promotion of Vraylar is evident from the notes entered by Allergan sales representatives. The Allergan call note system allows its sales representatives to enter detailed notes in the sales tracking software. The software allows sales representatives to enter in a free-form text box, and does not rely on drop-down menus or preset options. The call notes are meant to help representatives and their counterparts recall what was discussed on a sales call, look at before the next follow-up sales call, and hone their sales strategy. When its sales strategy is based on off-label promotion, however, those tactics get documented as well.

291. Allergan gave little guidance on how to fill out the call notes and different managers gave different directives on the issue. Relator's manager did not direct his sales representatives to enter call notes. In Relator's experience, this was because his manager knew how many off-label discussions were taking place with his representatives and he did not want any of this recorded in call notes accidentally. According to DM Burrier: "I look at some of the call notes that some of you are putting in and you don't need to be so specific.... I shake my head looking at some of these."

292. On October 7, 2019, Relator received a phone call from another representative in his district, Warren Valenta. Valenta, who Relator rarely talked with over the phone, explained that he was reaching out to everyone in the district after a ride-along day he had the prior week with DM Burrier. During that ride along, Burrier mentioned to Valenta that one of their competitors (representatives selling Latuda) had been "turning things in" on Allergan

representatives that could be related to off-label discussions/promotion of Vraylar. Burrier was apparently told this by his manager, RM Cox. Cox mentioned to him that lately twice as many potential compliance violations had been "turned in" on Allergan sales representatives.

293. The biggest concern that Valenta expressed was what call notes they were putting in as well as any e-mails they send to Burrier and management. Although it sounded as though Burrier did not directly ask Valenta to reach out to other representatives, he was very receptive to the idea when Valenta brought up that he would do this proactively. Burrier agreed that it may not be a bad idea to remind everyone to watch what they say and do in the field, and watch what is documented. Valenta said that it would help Burrier if he did not have to screen every e-mail that the district was sending to him for compliance related content.

294. The purpose of the call was to remind everyone in the district to be careful about documenting off-label discussions in e-mails and call notes. Relator's takeaway from the call with Valenta was that management had concerns about how vigilant Latuda representatives were being in the field. Allergan sales representatives' messaging to prescribers had been: "Replace Abilify and Latuda with Vraylar...." Allergan was cutting into the market share of Latuda, and they were fighting back.

295. After Relator received the call from Valenta, he had a talk with Matt Griffin on October 7, 2019. Griffin confirmed and reinforced things Relator had experienced with his manager's direction to talk off-label. The following exchange is illustrative:

> *Griffin*: I mean, there's so much in those notes that can get us fired, it's crazy. So, I don't blame them. I'm just stopping. If they want to call me up and get down on me. Go ahead. I'm all right.
>
> *Relator*: Well, no, we've talked, I don't think Garrett necessarily wants us putting in call notes for that reason.

Griffin: Yeah. You know, that's never come up. I don't recall in discussion. Has it with you? I don't think it's like... that's what the top priority is.

Relator: No. And I think he realizes we're potentially hearing and talking off-label and doesn't want it documented. I mean, isn't that your kind of assessment?

Griffin: Correct. And he talks off-label all the time, and he tells us... Like I said, if I recorded it half the shit he said he'd get fired tomorrow, I think. I mean, it wouldn't be one violation, it'd be a thousand violations. The shit he implies like that, that old.... The three week grant on our scores are better than this and implying that we could be used in depression. Hey, if it's depression, it should be... No, it's not just depression, its Bipolar Depression, Garrett.

Relator: Right. But he uses that pretty, pretty loosely.

Griffin : He does use that.

Relator: And wants us using it pretty loosely, too.

Griffin : Well, and he made the-he was... went so far as early on stated to us that, remember when you started to push it and I asked, I asked Chiu about that one day and he goes, "You can't, you can't take depression from an MDD patient or for a depressive patient and compare it to Bipolar Depression. Those are two different types of people." I remember Chiu saying that to me: "You cannot go that direction." He goes, "I use it there because I've seen some of the studies. But you shouldn't go out talking about it."

Relator: Yeah. Well, wasn't that during the launch of Bipolar Depression when Garrett was with you and he was trying push that on Chiu? Use it for depression, like use it for straight up depression or Adjunct Depression?

Griffin : Yep. He equated the depression being the same no matter what product you look at. I was like-

Relator: Based on what?

Griffin: Just based on the MADRS score, that if we can do that [bipolar] depression, we should be able to work in regular depression with patients, you know? I mean our MADRS scores are that good. That depression.... What Garrett was pretty much saying is, "Depression is Depression." Throughout the indication if it's depression, we worked. And you know what, he's probably right. We're probably... I mean I'm thinking we'll get the indication for it and we're probably right, but how can you say that [when] we don't have indications for it? I don't know how you can.

296. Despite the warnings, Allergan sales representatives still documented Allergan's off-label marketing schemes in their call notes.

297. Another manager, Tyler Moriarty, did ask his representatives to enter call notes after every call. These call notes back up the concerns Relator's manager had because they often show explicit off-label marketing.

1. Allergan Sales Representative Call Notes Reflect the Scheme to Promote Vraylar Off-Label as a Replacement for Competitor Drugs Which Had Completely Different Indications

298. The call notes demonstrate a frequent off-label marketing tactic used to promote Vraylar, what was dubbed the "Replace with Vraylar" strategy. Sales representatives were praised and rewarded for asking doctors to replace other atypical antipsychotics with Vraylar. This is despite the fact that Vraylar does not have the same indications as the drugs the representatives are suggesting should be replaced.

299. For example, a sales representative (Damian Stednitz) was consistently praised by management for asking health care professionals: "You should be using Vraylar in place of Latuda and Abilify."

300. The problem with this sales tactic is that Abilify and Latuda do not have the same indications as Vraylar. For example, Abilify has an indication for MDD; Vraylar does not. Abilify has an indication for pediatric use; Vraylar does not. Latuda has in indication to treat Bipolar Depression in pediatric patients; Vraylar does not.

301. In addition, Relator often saw call notes where sales representatives were using phrases and tactics that asked the prescriber to use Vraylar "in place of" or "in front of" competitor drugs. The sales representatives are also encouraged to use the tagline: "When you think of [competitor drug], think Vraylar instead." The issue with these tactics is that other atypical

medications like Seroquel, Abilify, and Latuda have different indications and uses. Making a blanket statement to replace Vraylar instead of what they are using implied that the medications have equivalent indications when they, in fact, do not. This is especially problematic when equating Vraylar to Abilify. Abilify has an indication for the adjunctive treatment of MDD, but the FDA specifically determined that Vraylar should not be approved for the treatment of MDD because of both a lack of efficacy and associated serious side effects with this use.

302. The coaching that Relator and his district received from DM Burrier was very consistently to ask health care professionals to "replace another atypical with Vraylar" or "add Vraylar 1.5 mg onto current drug regimen" for patients not at remission.

303. This language can be seen throughout the call notes of Relator's sales representative counterparts. For example, the call notes entered by Charles Register show the off-label promotion strategy at work.

304. Register's notes used "in front of" language in summarizing his call with Thomas Kefalas, MD from Northland Counseling Services located at 215 SE 2nd Avenue, Grand Rapids, Minnesota 55744. The call notes say that "[n]o starts, discussed VY [Vraylar] infront of Abilify for patients she thinks can be doing better, discussed the dosing and quick it on the BPD data."

305. Register's call notes of a visit with Michael Keegan, CNP of Stone Creek Psychiatry located at 7945 Stone Creek Dr # 130 Chanhassen, Minnesota 55317, talk explicitly about replacing all Latuda and Abilify use with Vraylar: "Talked to him about the BPD data, knew about the indication but nothing really about the data, went over the studies with him an how it now has full spectrum coverage, agreed how awesome that was and how the first dose is the therapeutic dose, agreed there wasn't a reason to use Abilify of [sic] Latuda anymore unless coverage was an issue. Agreed to start patients on it over the next two weeks to get more

comfortable with coverage." These call notes illustrate how the "replace with Vraylar" strategy an effective off-label message.

306. Register also used "think of Vraylar" instead of other, differently-indicated drugs in the call notes for a visit with Tiffany Hurt, PA from Nystrom & Associates located at 11010 Prairie Lakes Dr, Eden Prairie, Minnesota 55344. The notes state: "Went over every time she's thinking Abilify think VY [Vraylar], went over the Durgan study and touched on the Metabolic as well, coverage was a concern so also touched on that."

307. Register's call notes for Nathan Hockert, PA from Nystrom & Associates located at 1900 Silver Lake Rd Northwest, New Brighton, Minnesota 55112-1786 have similar "in front of" language. They state: "Came in briefly. Knows he needs to give Vraylar a try. Pushed him to give it a fair shot and he'll see the benefits. Writes a lot of abilify – use in front or switch."

308. For Harvey Green, MD, located at 825 Nicollet Mall S1548, Minneapolis, Minnesota 55402 the call notes include the "in front of" language as well: "Discussed the BPD studies, positioned it in front of abilify and Latuda and went over full spectrum coverage for his patients with the first does, went over the SE profile with him as well." Another note for Dr. Green is similar: "Discussed using VY infront [sic] of abilify going forward, had someone coming in this afternoon he wants to get started. Gave the nemeth study, follow up to hear his thoughts!"

309. The notes for Twila Germanson, MD from Germanson MD Psychiatry LTD, located at 13911 Ridgedale Dr Ste 450, Minnetonka, Minnesota, 55305 continue the trend: "Great convo about VY, went over new studies and positioned it in front of Latuda and Abilify and she agreed that it made sense, asked about metabolics and SE, said she didnt see a reason why she wouldn't use it first every time."

310. The notes for Zvi Frankfurt, MD from West End Psychiatry located at 5353 Gamble Dr #335, Minneapolis, Minnesota 55416 show the same off-label sales tactics: "Went over copay cards, positioned VY in front of Abilify for his patients and he loved the coverage, 3 copay cards in hand!"

311. The notes for Register's calls on Larry Berger, MD from Berger Psychiatric Services, LLC located at 7525 Mitchell Road, Suite 200, Eden Prairie, Minnesota 55344 are further evidence of the "in front of strategy": "Started out saying he doesnt use it and all his patients are stable, was able to get him to open up and talk about his practice and that there is a place for it in his practice. Positioned it infront of Abilify, copay cards and samples in hand. Discussed the metabolics with him as well as the efficacy. Follow up!"

312. Likewise, Register's notes for his call with Pastor Colon, MD from Natalis Counseling & Psychiatry Solutions located at 1600 University Avenue West, Suite 12, St. Paul, Minnesota 55104 are more evidence of the off-label tactic: "Colon was basically in and out but did sit and listen when I was talking about the baseball analogy, liked the dosing and positioned in as a first line option for him infront of Seroquel and Latuda since he never uses abilify."

313. The notes describing Register's sales call with Paul Ekberg, DO from the Associated Clinic of Psychiatry located at 4027 County Rd 25, St Louis Park, Minnesota 55416 clearly show how the "in front of" strategy leads to confusion and off-label usage: "Discussed the new studies, said that 'there's no need to use Latuda or Abilify anymore' love that it was one pill that covers full spectrum with the first dose. Agreed to use it infront of Latuda and Abilify over the next two weeks." Given their different indications, Vraylar cannot be simply substituted for Latuda or Abilify. Thus, this note makes clear how the "in front of" sales tactic promotes off-label use.

314. The "Replace with Vraylar" sales strategy of positioning Vraylar "in front of" or in place of other differently indicated drugs is selling Vraylar for indications it does not have. Thus, the strategy encourages prescribers to use Vraylar in situations where it is not appropriate thereby endangering patients, patients who there is no evidence they would even gain any benefit from the drug.

2. Allergan Call Notes Detail Its Scheme to Promote Vraylar Off Label to Health Care Providers Treating Only or Predominantly Children and Adolescents

315. Register's call notes for Kim Holtmeier, MD, from BHSI located at 8441 Wayzata Blvd, Suite 140, Golden Valley, Minnesota 55426, not only demonstrate the "in front of" language ("Positioned VY [Vraylar] in front of Abilify, she liked everything about it but said coverage was the only thing really holding her back. She admitted she didn't look at insurance plans when a patient comes in so I told her over the next month I want her to reach for VY and not worry about coverage because its there."), they demonstrate its scheme to sell Vraylar to health care professionals who treat children and adolescents.

316. Register's call notes reflect the scheme to sell Vraylar illegally to treat pediatric patients. Dr. Holtmeier's areas of practice are: "Diagnostic evaluations and medication management for children, teens, and young adults."[115] Vraylar is not indicated for use in pediatric populations for any use. On the other hand, Abilify can be used with pediatric populations.

317. Similarly, Register's call notes of a visit to Patricia Blummenreich, MD from First Street Center located at 540 E 1st St, Waconia, Minnesota, 55387, reflect the "think of Vraylar" strategy. The notes state: "Discussed patients that are still struggling, also positioned every time

[115] Golden Valley Providers, BHSI, https://bhsiclinics.com/golden-valley-staff.

she's thinking Abilify think VY." Simply put, Vraylar cannot be marketed as a replacement "every time" Abilify is used given the different indications of Abilify and Vraylar.

318. Register's call notes for his call with Nicole Larson, CNP, from Nystrom & Associates located at 4300 West 147th Street Suite 204 Apple Valley, MN 55124 show the off-label promotion as well. First, Nicole Larson treats children; her clinical interests are "Pediatrics: Depression, Anxiety, OCD, Bipolar Disorder, and ADHD."

319. The call notes for the sales call on Larson illustrate the conflation between the indicated use of Vraylar (Bipolar Depression) and its lucrative, but off-label use (MDD/unipolar depression). The notes state: "Encouraged by bpd data. Likes data on depressive symptoms. Has patients she wants to start." The "bdp data" (*i.e.,* the Bipolar Depression data) has no bearing on depressive symptoms from MDD. Promoting Vraylar to treat depressive symptoms alone is illegal, off-label promotion with potentially deadly adverse events.

320. The call notes show Allergan's off-label marketing scheme was consistent and widespread – exactly why some managers discouraged the use of them. Furthermore, the call notes detail how Allergan sales representatives were selling Vraylar illegally in numerous ways such as for treatment depressive symptoms alone and as a replacement for competitor drugs with additional indications that Vraylar does not have (like pediatric use or to treat adjunct depression). Yet, the call notes show not only that these tactics were being used, but the notes show these illegal off-label sales tactics being targeted at prescribers who treat children and adolescents. The off-label targeting of the prescribers with pediatric patient populations is particularly egregious given the effects powerful atypical antipsychotics like Vraylar have on children.

H. Off-Label Promotion Is Continuing Nationwide at the Direction of Allergan Sales Management

321. Allergan's illegal off-label promotion is nationwide and ongoing. Relator went to Allergan's Phase 3 Training in St. Louis, Missouri on September 24-25, 2019. The attendees at the training consisted of about 50 Vraylar sales representatives, broken down between Primary Care sales representatives and Specialty Sales representatives. The goal of this training was to sharpen skills on product knowledge, competitor products, selling skills, and business acumen.

322. DM Garrett Burrier was the primary facilitator for the Vraylar training on September 25, 2019, along with another DM, Chris Gannon, co-facilitating. There were about fifty (50) representatives in this training class that went from 8:00 A.M.to 3:00 P.M. Also present in the room and jumping in to help facilitate were Matt Britt (Manager of Field Sales Force Effectiveness), RM Josh Cox, VP of Sales Susie Brandt, Trainer Jim Kraschel, and about four other DMs from around the country.

323. In that training, Burrier made numerous comments encouraging off-label promotion of Vraylar. Relator took notes of the various comments. For example, Burrier at one point coached them to make the unsubstantiated, off-label claim that Vraylar would remit (cure) Bipolar Disorder: "If they [patients] are not at remission, they need to be on Vraylar!" Burrier also suggested another sales message to have with providers: "Dr., with Vraylar, Abilify should never be used again!"

324. At one point, DM Burrier made the completely unsubstantiated claim that sales representatives were to use in detailing Vraylar: "If patients are not in remission, they should try Viibryd or Vraylar. This is when I am asking you to use Viibryd." This claim is false. There is no substantial evidence that the use of Viibryd or Vraylar results in remission.

325. Burrier gave another completely false selling message, saying: "Doctor, you see depressed patients every day…. We have a 50% reduction in MADRS scores. I don't even want you using Abilify anymore. Well, okay, only if they have failed Vraylar first. Can we take it to the next level and use Vraylar in place of Abilify? Abilify is only effective when you have an antidepressant onboard!"

326. Burrier also gave suggestions on how the sales representatives could sell against Seroquel, an atypical commonly used at low doses to help patients sleep: "How do we sell competitively? We talk about the function of the patient (sleepy and foggy). Doctors can just add Vraylar 1.5 mg to Seroquel. Add 1.5 mg and slowly titrate patients off Seroquel. We got into trouble early on after launch with having docs switch off Seroquel. It adversely affected patients' sleep." There is no substantial evidence supporting claims for the use of Vraylar as a sleep aid.

327. DM Chris Gannon added his own false sales message to use with Vraylar: "'Doctor, Vraylar treats depression better than any SSRI in your sample closet!' If the doctor says: 'Whoa, wait a minute. Are you saying you have the depression indication?' You could clarify and say: 'Well, no, Doctor. We are talking about Vraylar that has been out for four years now, you know that.'"

328. Again in this session, the sales representatives were encouraged to promote Vraylar to treat symptoms, not an actual indication. The sample ask of a doctor in their details was: "Dr., what symptoms are you trying to address with Product X?" Then the representative was to go to the sales aid and show all the manic and depressed symptoms that Vraylar treats.

329. One of the representatives, Aleisha (last name unknown) did a practice role play. Her sales message was: "Doctor, now that we have depression data, patients can get better, quicker within one week." She specifically used the term "Depression," not "Bipolar Depression," which

is consistent with how managers insisted representatives were to talk about their new Bipolar Depression indication. Representatives were directed by their managers to say and talk about "depressive" symptoms or patient types when discussing Vraylar instead of what the indication really is, which is Bipolar Depression.

330. Aleisha later gave another role play in a smaller group Relator was in. Again, her message was: "Dr., since the new depression data has come out, I want you to think about your depressed patients." Again, she did not use the term "Bipolar Depression." At no point did any of the managers step in to clarify and instruct that the sales representatives need to be using the term "Bipolar Depression."

331. At the training, Relator talked to a Primary Care representative from Quad Cities, Iowa about how she and her colleagues were selling Vraylar to PCPs. Her response was consistent with how Relator and the Specialty Representatives are selling to psychiatrists and what Relator had heard from other representatives.

332. She had been selling and talking about symptoms with PCPs to try to get them to use Vraylar, not about the Bipolar Depression indication. Specifically, she was talking about treating depressed symptoms in patients.

333. Her other strategy to try to get PCPs to try Vraylar was looking for patients that have been on two to three antidepressants and are not at goal.

334. Similarly, it was common for Allergan managers like Garrett Burrier and Tyler Moriarity to profile the patient that had failed two or three other antidepressants as being a Vraylar patient. The picture they painted was that, if a patient got a partial or non-response from an SSRI (anti-depressant), there must be something else going on with that patient. Managers never recommended that sales representatives talk to prescribers about using DSM criteria or screening

tools to help them make an accurate diagnosis of Bipolar Disorder and/or Bipolar Depression – *i.e.*, the indicated uses of Vraylar. Instead, the managers coached sales representatives to detail doctors with the pitch that patients who were non-responsive to SSRIs should use Vraylar despite the usage being off label in many instances.

I. False and Misleading Off-Label Promotion of Vraylar Is Company-Wide

335. Allergan's continued off-label promotion of Vraylar was not isolated conduct by a handful of rogue employees. Other Allergan sales representatives throughout the country also have been instructed to sell off-label and to target PCPs with the illegal message.

336. Echoing Relator's experience, one Vraylar sales representative posted concerns on the pharmacy sales representative message board CafePharma on March, 13, 2019, making clear that Allergan is widely viewed in the pharma industry for its management's aggressive and illegal behavior:

> How obvious is it that management is clearly pushing reps to talk about using Vraylar off-label for depression when the direction given during every meeting and call in is to ask physicians to use in place of abilify. And pushing reps to grow Vraylar in Primary care where it is very well known that they don't treat ACUTE mania or mixed episodes or Schizophrenia. Giving us bogus A targets to call on who barely prescribe any atypical agents...not likely they would actually be treating patients that fall within our indication. The last thing Allergan needs is to have compliance issues! Seems like no one cares anyways.

337. The message board thread continued with other examples of off-label promotion from other sales representatives. One user posted in response to the original post: "Direction from CNS Management to pull a list of top SSRI doctors and target them for Vraylar and not mention that Vraylar is an antipsychotic or what it's indications are to PCPs, I would say is all evidence."

338. Another post a few weeks later on April 4, 2019 said: "Obviously, more evidence that upper management is clueless to think shit like this won't bite them in the butt with an off-label promotion fine."

339. A separate message board thread also noted the problem of Allergan's off-label promotion of Vraylar. As one user wrote on April 9, 2019:

> I seriously think upper management is totally clueless to think it makes good business sense to add yet another rep to sell Vraylar in primary care offices. If this was such a great market to sell antipsychotics wouldn't Rexulti and Latuda have reps selling there too?? Abilify had augmenting MDD indication for quite awhile before it went generic yet didn't use resources to market there. I already have quite a few pcp on my panel that show up for 3 or less antipsychotics written in a 13 week period and they look at me like I have lost my mind asking them to use Vraylar. Now we are going to have even lower volume targets added??? Makes no sense at all.

340. Another user commented on the same thread a day later on April 10, 2019 saying: "Vraylar is not a primary care drug. Period. They are not trained to differentiate bipolar among all the other mood disorders."

341. There have been even more posts recently. On November 8, 2019, a user started a thread entitled "Vraylar for MDD." The first post asks: "Anyone else feeling pressured to sell Vraylar for unipolar depression? Feels like the only way to make the numbers. Thats where most of the business seems to be." Another user definitively replies: "Yes for sure! I've been led many many times to sell off-label by my DM."

342. Even the competitor company employees seem to know this is what is going on. One post remarked: "Everyone in this specialty knows about Allergan pushing Vraylar for MDD. Its no secret, doctors talk openly with me about it and we laugh about the high EPS rates. … Incredible that you guys put Atypicals in the hands of PCP reps given the risks."

J. Allergan's Off-Label Promotion Was Particularly Dangerous Because Allergan Covered Up Serious Adverse Events, Including Numerous Deaths

343. Since the launch of Vraylar in 2015, there have been a total of 1,415 adverse events reported to the FDA, 266 of which were labeled as "serious cases," including the 26 reported deaths following a prescription of the medication. The number of reported adverse events increased dramatically in correlation with Vraylar's new Bipolar Depression indication, jumping from 315 reported events in 2018 to 726 reported events in 2019. Also, since Vraylar gained the Bipolar Depression indication in June 2019, the reported deaths due to Vraylar has increased substantially: 15 of the 26 deaths have occurred since June 2019. This is a drastic spike in deaths because 15 deaths after Vraylar gained the new indication occurred in a substantially shorter time frame --11 deaths in forty-four (44) months from September 2015 to June 2019; 15 deaths from only eight (8) months from June 2019 to February 2020.

344. A number of serious adverse events reported to the FDA by both consumers and health care professionals demonstrates the dangerous harm caused to child and adolescents patients following a Vraylar prescription (12 non-serious cases for 3-11 years old, 85 cases for 12-17 years old). Several representative adverse event examples include:

- On July 6, 2018, a healthcare professional reported that a 14 year old boy suffered from seizures after taking a Vraylar prescription for biopolar depression. (FDA Case ID 14720169). Vraylar is not approved to treat adolescents.
- On August 21, 2018, it was reported that a 15 year old was hospitalized as a result of serious aggression after taking Vraylar for the off-label use of Major Depression Disorder. (FDA Case ID 15260508). Vraylar is not approved to treat adolescents.

- On October 19, 2019, it was reported that a 14 year old girl, prescribed with a combination of Abilify and Vraylar for Bipolar disorder, was hospitalized after experiencing suicidal ideation and hallucinations (FDA Case ID 16915235). Vraylar is not approved to treat adolescents.

345. Likewise, other serious adverse events reported to the FDA demonstrate the often catastrophic patient harm caused as a result of prescribing Vraylar for the off-label use to treat Major Depression Disorder (MDD) and anxiety, including the following reported suicides:

- On September 30 2019, it was reported that a male, not specified by age, died by suicide after receiving a prescription of both Vraylar and Rexulti to treat his MDD. (FDA Case ID 16866062) MDD is not an approved Vraylar use.
- It was reported that in September 2018 a 47 year old male died by suicide as result of his Vraylar prescription for his depression and anxiety. (FDA Case ID 16865841) Vraylar is not approved to treat depression or anxiety.
- On October 14, 2016, it was reported that a 63 year old male died by suicide after taking Vraylar for his MDD. (FDA Case ID 12847896). Vraylar is not approved to treat MDD.

346. Promoting a powerful drug like Vraylar off label is dangerous enough on its own. Allergan, however, took its conduct a step further and instructed its sales representatives not to accurately or fully report Vraylar adverse events.

347. Allergan's own Adverse Events Reporting Policy provides detailed instructions about how to collect information about and report adverse events. Yet despite explicitly recognizing its "ethical and legal responsibility" to report adverse events, Allergan routinely violated its own policy. By doing so, Allergan downplayed the dire safety risks associated with

off-label use of its products like Vraylar for indications that were much broader than those approved by the FDA.

348. Relator's first experience with this abhorrent conduct was during his onboarding and initial training. During a meeting with two other new hires, Matt Munson, a sales representative for Minnesota and Matt Griffin, a sales representative based out of South Dakota, one asked a question about what to do if a sales representative hears about an adverse event. Despite the importance of reporting adverse events being nearly universally stressed at other pharmaceutical companies, DM Burrier downplayed the importance of adverse event reporting and tried to brush it off. His comments were essentially that "Adverse Events from psychiatric disorders alone or with other medications are common. If we were to report every adverse event we heard in one day, we would be on the phone all day." The guidance from DM Burrier was to report adverse events only every now and then. Relator talked to one of the other new hires the next day about how out of the norm it was to hear that they should not be reporting all adverse events, especially when the instructions came directly from a manager. Both were shocked at what they heard.

349. On February 22, 2019, Relator's manager spent a day in the field with him. A psychiatrist (Robin Bixler, DO from West End Consultation Group located at 1550 Utica Avenue South, Suite 450, St. Louis Park, Minnesota 55416) mentioned that she started a patient on Vraylar and that the patient was experiencing an adverse event. She was unsure if the patient would be able to continue on Vraylar or whether she would need to switch to another drug. Relator's manager asked Dr. Bixler what dose the patient was taking, mentioning that some other psychiatrists were dosing Vraylar every other day (an off-label use) to minimize/reduce the risk of adverse events. At no time during the call did Relator's manager ask for more info about the patient or get any info

for reporting an adverse event. After the call, he did not discuss with Relator the need to report this.

350. On May 15, 2019, Relator's primary care counterpart (Kevin Markgraf) spent his first day selling in the field with his manager (Tyler Moriarty). Relator talked to Markgraf at the end of the day to see how things went. Markgraf relayed that on one sales call to Daniel Durbin, PA from Nystrom & Associated located at 7300 147th St W Ste 204 Apple Valley, Minnesota 55124, the physician told them that three patients he used Vraylar on had adverse events including "crazy migraines" and a patient becoming extra manic. At no time did Moriarty step in to ask if these events had been reported nor did he follow industry protocol in gathering information from the physician about the patients and adverse events (*e.g.,* patient demographics, dosing of Vraylar, adverse events experienced, etc.).

351. Likewise, on May 21, 2019, Regional Sales Director Josh Cox spent a half day in the field with Relator. One provider they called on, Leigh Hagglund, NP, from Truyu Health & Wellbeing located at 700 Twelve Oaks Center Drive, Suite 700, Wayzata, Minnesota 55391, reported a patient that needed to discontinue Vraylar due to an adverse event, Akathisia. The only question Cox asked was what dose the patient had been taking. He never discussed the need to collect more information about this adverse event or to report this as an adverse event.

352. Given the explicit directions from management not to report Vraylar adverse events of which sales representatives had become aware, the number of reports publicly provided to the FDA is undoubtedly far from accurate. Indeed, it has been estimated that only 1 percent to 10 percent of adverse events are ever reported to the FDA.[116]

[116] Nebeker, et al., *Clarifying Adverse Drug Events: A Clinician's Guide To Terminology, Documentation, and Reporting*, 140 Annals of Internal Medicine, 1795–801 (2004).

353. However, even the limited number of reports reveals the often catastrophic patient harm caused by the off label prescribing of Vraylar.

354. Allergan sales managers' indifference to adverse events only underscores the lengths Allergan is willing to go to in order to keep the sales of Vraylar high, even if the sales for off-label (or any) use causes patients serious harm.

VIII. ALLERGAN'S USE OF KICKBACKS TO PROMOTE VRAYLAR, INCLUDING FOR OFF-LABEL USE

355. Allergan used kickbacks in the form of speaker payments to expand the use of Vraylar, particularly the off-label use of Vraylar. Allergan's illegal kickbacks took two primary forms: 1) paying prescribers who prescribe Vraylar off-label to speak about using Vraylar off-label; and 2) arranging for "sham" speaker programs as a reward and/or inducement for the speaking physician's prescribing of Vraylar. There is no question that Allergan doled out such largesse in order to induce prescriptions of Vraylar, a clear violation of the AKS.

356. In recent years, as enforcement of the AKS has increased, many pharmaceutical companies have closed down the most egregious violations. The voluntary PhRMA Code on Interactions with Healthcare Professions ("PhRMA Code") that the pharmaceutical industry adopted in 2008 prohibited drug companies from making excessive payments to key opinion leaders ("KOLs") and required the companies to receive some true educational feedback or advice when they paid KOLs to act as "consultants."[117]

357. The PhRMA Code prohibits signatories from providing "entertainment or recreational activities to healthcare practitioners who are not employees of the companies in any

[117] Code on Interactions with Health Care Professionals, PhRMA (September 2019), https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/A-C/Code-of-Interaction_FINAL21.pdf.

context, including situations where those practitioners are providing a legitimate service to the companies, such as when they act as bona fide consultants on an advisory board or are trained at a speaker-training meeting."

358. But the fact remains that many KOLs are up for sale, and the easiest way to acquire brand loyalty is to buy it. Since it launched Vraylar in 2015, Allergan has engaged in marketing programs that had no real corporate purpose other than to hand out bribes to high-level prescribers with the expectation that these KOLs would express their gratitude by prescribing more and more Vraylar.

359. Allergan has used Vraylar speaker training to "educate" KOLs about Vraylar off-label uses, and to reward their prescribing the drug off-label.

360. Paying lucrative speaker fees was a key part of Allergan's marketing of Vraylar to psychiatrists who, as a group, earn less in base salary most other medical specialists.[118] In 2019, for example, average compensation for psychiatrists was $260,000, considerably less than the $482,000 earned by orthopedists and barely more than the $243,000 earned by doctors practicing internal medicine. Many psychiatrists, however, supplement this income with consulting arrangements with drug makers, traveling the country to give talks about drugs to other doctors for fees generally ranging into the many thousands of dollars.

361. Allergan routinely paid exorbitant amounts to its speakers. In total, in just 2016 Allergan spent $6.99 million for payments to prescribers related to Vraylar.[119] That amount made Allergan's payments to 19th most overall for a single drug. By 2018, which is the most recent data

[118] Kane, Leslie, *Medscape Psychiatrist Compensation Report 2019* (April 24, 2019), https://www.medscape.com/slideshow/2019-compensation-psychiatrist-6011346.
[119] Ornstein, Weber, and Grochowski, *We Found Over 700 Doctors Who Were Paid More Than a Million Dollars by Drug and Medical Device Companies,* PROPUBLICA (Oct. 17, 2019), https://www.propublica.org/article/we-found-over-700-doctors-who-were-paid-more-than-a-million-dollars-by-drug-and-medical-device-companies.

available, Allergan boosted its spending on doctors to $9.68 million dollars.[120] This raised Allergan's spending on Vraylar to the 12th most overall.

362. The large amount of money Allergan was willing to spend on payments to doctors related to Vraylar is reflected in large sums paid to individual speakers. The top ten speakers Allergan paid in 2018 to promote Vraylar all made substantially more than $100,000 for the year, potentially increasing their base salaries by over 50%. In fact, the top payment amount for 2018 was for nearly $200,000 to Stephen Ellen, a psychiatrist from Nashua, New Hampshire. In 2019, Dr. Ellen did not slow down and spoke over 75 times – an average of over 6 speaker events per month.

363. The top ten speakers in 2018 for Vraylar by dollar amount were:

Name of Physician	Type of Practice	Location	2018 Speaker Payments Related to Vraylar
Stephen Ellen	Psychiatry	Nashua, NH	$199,000.00
Gustavo Alva	Psychiatry	Costa Mesa, CA	$165,000.00
Todd Gates	Psychiatry	Haines City, FL	$164,000.00
Vladimir Maletic	Child & Adolescent Psychiatry	Greer, SC	$164,000.00
Gregg Friedman	Psychiatry	Hallandale Beach, FL	$157,000.00
Prakash Masand	Psychiatry	Syracuse, NY	$155,000.00
Jeffrey Hansen	Psychiatry	Vancouver, WA	$154,000.00
Richard Petty	Psychiatry	Loganville, GA	$142,000.00
Andreas Sidiropoulas	Psychiatry	Detriot, MI	$140,000.00
Rakesh Jain	Psychiatry	Lake Jackson, TX	$136,000.00

364. Todd Gates, DO from West Melbourne, Florida demonstrated the effectiveness of paying these amounts to prescribers. His prescriptions increased from $31,717.12 to $115,381.28

[120] *Id.*

from 2016 to 2017 and, at the same time, his promotional payments increased from $44,435 to 96,260.00. For an additional investment of $51,825 in payments to Gates, Allergan reaped an additional $83,664.16 in prescriptions.

A. Paying Kickbacks to Prescribers Who Wrote Vraylar for Off-Label Uses

365. Promotional programs funded and conducted by pharmaceutical companies are highly regulated by the FDA. Essentially, promotional educational presentations must be "on-label," presenting only information about FDA-approved uses contained in the product's package insert. Promotional talks must also contain "fair balance"— *i.e.,* a discussion of the risks and benefits of the drug, including adverse effects, precautions, and warnings. Above all, promotional programs must be truthful and not misleading. All presentation slides, whether provided by the pharmaceutical company or developed by the speaker, should be designed to meet these requirements.

366. A narrow exception to the "on-label" rule exists for promotional programs. Speakers may answer questions about unapproved drug uses so long as the questions posed by the audience are unsolicited. Speakers should clearly advise the audience that the answer is outside the scope of approved labeling and that they are speaking from independent medical judgment. Questions should be answered briefly, to avoid unnecessary off-label discussion, and then the discussion should be guided back to the originally planned, on-label presentation.

367. Despite these rules, Allergan still instructs its speakers to talk about the off-label uses of Vraylar, especially depression given its lucrative market. An April 2019 post on CafePharma is evidence of Allergan's instructions to speak about off-label uses of Vraylar:

> Competition here. One of my speakers told me used to speak for vraylar and during training they were urged to throw in how vraylar works for depression. I didnt even have to prompt him! My local allergan rep takes the PI out of his literature drops

> too. I feel like the hammer will drop on you guys and if you were smart youd jump ship.

368. Relator saw first-hand Allergan management's desire for speakers to talk about Vraylar's off-label uses. On the June 25, 2019 call referenced above, RM Cox explained his interaction with 20 to 30 Vraylar speakers who supported selling well beyond its limited Bipolar Depression indication:

> I asked probably 20 or 30 doctors that were at the speaker training this weekend: "How would you sell this?" Their answer was the exact same. They said as an antidepressant. It's just the data, the data's as good as any antidepressant out there. Obviously they know it's indicated for Bipolar, but they were like, "you've just got to get the doctor to think about depression not... because they're not going to touch mania, particularly in primary care or even any part of that." So I think you guys are dead on. It has to sound different than it has over the past couple of months.

369. Just as Allergan management has instructed its sales representatives to promote Vraylar for depression generally and not just its indicated use to treat Bipolar Depression, Allergan has encouraged its paid speakers to do the same off-label marketing.

370. Furthermore, prescribers who treat patient populations that either are impossible to treat using Vraylar on-label (*e.g.,* child psychiatrists) or treat patient populations that are highly unlikely to treat using Vraylar on-label (e.g., primary care physicians) are not appropriate recipients of Allergan speaker payments because it necessarily invites off-label discussion in their presentations. Indeed, what on-label Vraylar information could those speakers credibly even talk about?

371. Nevertheless, one of the top paid speakers in 2018 (Vladimir Maletic, MD from Greer, South Carolina) is a specialist in child psychology. Healthgrades describes him as a "child

& adolescent psychiatry specialist."[121] Despite that specialty, Allergan made Dr. Maletic one of their most-highly compensated shills.

372. Allergan routinely has used off-label prescribers as paid speakers for Vraylar. Allergan's own internal 2019 CNS speaker list includes examples of child and adolescent psychiatrists who Allergan paid to promote Vraylar:

FIRSTNAME	LASTNAME	DEGREE	SPECIALTY	AFFILIATION/PRACTICE NAME	CITY	STATE	TOTAL PROGRAMS IN CALENDAR YEAR
Muhammad	Munir	MD	Child & Adolescent Psychiatry, Psychiatrist	Harmony Medical Associates	Fishers	IN	17
John	Gelinas	MD	Child & Adolescent Psychiatry, Psychiatrist	Family Study Center, Inc.	Danbury	CT	8
Steven	Dyckman	MD	Child & Adolescent Psychiatry, Psychiatry/Neurology	JFK Hospital	Brunswick	NJ	2
Said	Jacob	MD	Pediatric Psychiatry/Child Psychiatry, Psychiatry/Neurology	Chief of Staff - Aurora Charter Hospital, Medical Director Chief of Staff / Medical Director - Aur	Glendora	CA	8

[121] Dr. Vladimir Maletic, MD, Healthgrades, https://www.healthgrades.com/physician/dr-vladimir-maletic-3hkf2.

373. Vraylar has a black box warning about using the medication with elderly patients. But there are also numerous examples of geriatric psychiatrists being paid to speak about Vraylar for Allergan's CNS division:

FIRSTNAME	LASTNAME	DEGREE	SPECIALTY	AFFILIATION/PRACTICE NAME	CITY	STATE	TOTAL PROGRAMS IN CALENDAR YEAR
Mark	Shukhman	MD	Addiction Medicine, Geriatric Psychiatry, Psychiatrist	Associates in Psychiatric Wellnes, LP; Advocate Lutheran General Hosp; NorthShore Health systems	Skokie	IL	4
Martin	Guerrero	MDIR	Forensic Psychiatry, Geriatric Psychiatry, Psychiatrist	National Smart Health LLC	El Paso	TX	24
Jason	Kellogg	MD	Geriatric Psychiatry	ATP Clinical Research	Newport Beach	CA	30
Tulio	Ortega	MD	Geriatric Psychiatry	Adjuntive Clinical Professor, SUNY at Buffalo, Medical Director - Orleans County Mental Health Servi	Rochester	NY	1
Jose	Gamez	MD	Geriatric Psychiatry, Psychiatrist, Psychiatry/Neurology	Palmetto General Hospital,	Hialeah	FL	6
Hiten	Kisnad	MD	Geriatric Psychiatry, Psychiatrist, Psychiatry/Neurology	Beaches Psychiatry	Jacksonville	FL	4

374. Importantly, the descriptions of each speaker's clinical specialty is from Allergan's own internal list. Allergan thus knows full well that these doctors, given their specialties, cannot be promoting Allergan on-label, but pays them speaker fees as bribes for their off-label prescribing regardless. The conduct is particularly egregious because of the serious dangers of using Vraylar with pediatric and geriatric populations. For Allergan, though, the money to be made from more Vraylar prescriptions outweighs its concerns about the risk of patient harm.

B. Allergan Pays Kickbacks in the Form of Sham Speaker Programs

375. In addition to paying prescribers for off-label speaker programs, Allergan pays speakers as a way to reward Vraylar prescriptions or to induce even more prescriptions of Vraylar.

The effect of these annual six-figure payments on physician prescribing has predictably and intentionally led to the inducement of Vraylar prescriptions.

376. Allergan management pressures sales representatives to find speakers to promote Vraylar because Allergan knows that the payments to the speakers themselves are worth the investment, regardless of the speaker's quality or message.

377. For example, DM Burrier often pressured Relator to recruit Dr. Sujit Varma. Dr. Varma is a psychiatrist from Minnesota Mental Health Clinics, 1000 Radio Drive, Suite 210, Woodbury, Minnesota 55125. DM Burrier did not insist on Dr. Varma as a speaker because he is a compelling speaker, has unique insight, or because he is a good presenter. Rather, the attempt to get Dr. Varma as a speaker was to encourage him to prescribe more Vraylar – *e.g.,* to "jump start" his Vraylar prescribing. The speaker payments are thus merely a sham and are a classic kickback aimed at inducing Vraylar prescribing.

378. Allergan's attitude about using speaker programs simply as kickbacks to encourage the speaker's own prescribing are laid out explicitly in text messages from DM Burrier. On April 12, 2019, DM Burrier texted sales representatives, including Relator: "I have money for one or two more programs for Q2. Also I've received some good speaker nominations from a few of you. Honestly…..it's not just about them speaking in Vraylar but getting them trained and educated in Vraylar. Let's get this going."

379. Burrier's focus on the speakers getting "trained and educated in Vraylar" shows how the speakers that Allergan targeted were not widely respected psychiatrists or experts with atypical antipsychotics. Rather, they were prescribers who would prescribe Vryalar more if Allergan paid them kickback in the form of speaker fees.

380. Another example of the sham speaker payments Relator witnessed was with Dr. Thomas C. Winegarden, a psychiatrist from Chanhassen, Minnesota. In text messages, DM Tyler Moriarty encouraged Relator and other sales representatives to find speakers who would be receptive to Allergan's kickbacks. On September 12, 2019 DM Moriarty texted "What is quarter 4 speaker programs look like?" Relator answered "Nothing in books yet." Moriarty's response put the pressure on: "Gotta get moving. We just got the list and you are Charlie are one of very few that have nothing in the books. Need to get winegarden programs."

381. Relator, who was all too familiar with Winegarden's lackluster speaker skills, responded: "Have you heard Winegarden speak?" The message was that Dr. Winegarden was a terrible presenter and would not provide any value as a speaker.

382. Yet, Moriatry did not care. After all this was a kickback, not a legitimate speaker payment. His response was: "Gotta get him something. He took off work to train. If they train they need at least one program. Take him to a more unimportant clinic." The clear intent was to pay Winegarden for his prescribing, not his speaking.

383. Relator did as he was instructed and the kickbacks to Winegarden continued. On June 26, 2019, Relator sent a seemingly innocuous e-mail to DM Josh Cox and DM Garrett Burrier. Relator had taken Dr. Winegarden to an "unimportant" clinic to present on Vraylar. Relator wrote in the e-mail to the two managers that Dr. Winegarden's "skills as a presenter still suck, but I bring him onto to present at this one clinic because him and Dean Knudson go back 20+ years and he won't do any harm here."

384. The next day, on June 27, 2019, Relator got a call from Burrier directing him not to put such messages in writing, but instead to deliver such messages orally. Burrier warned Relator not to send e-mails like the one he had sent about Dr. Winegarden. Burrier explained that

e-mails like this could be misconstrued as describing an illegal kickback: "Oh you're just paying him because it's no harm bringing him to this office. So we're just going to pay him, to pay him to speak. And so, it could be quid pro quo."

385. DM Burrier's point on the phone call was exactly right. There simply was no other reason to pay Winegarden to speak other than to disguise the kickback to him. By putting information about the illegitimate nature of the payment in writing, Relator had jeopardized the kickback arrangement by documenting Winegarden's futility as a speaker.

386. Furthermore, rather than DM Burrier emphasizing what would be appropriate and compliant behavior, he instead provided Relator with instructions not to put anything in writing – *i.e.*, how to cover up potential compliance issues. Burrier told Relator that all e-mails are monitored by Allergan so he should not be putting anything in writing. In Burrier's own words: "But just make sure moving forward, there's no documentation on any e-mail servers, anything like that, whether it's messaging or speaker programs, or anything that someone could construe some other way because if his attorney gets that, you're fucked."

387. DM Cox also responded to Relator via e-mail, but never connected with Relator in person. The e-mail acknowledged that DM Burrier had "reached out" to Relator on the issue, but otherwise concealed the issue with seemingly innocent language.

388. Not only did DM Burrier confirm that the payments were a kickback to Winegarden, DM Burrier swept the e-mail under the rug instead of ensuring that they were engaged in compliant behavior. Not only that, Burrier took the incident as an opportunity to remind Relator to avoid leaving a paper trail of potentially illegal behavior.

IX. ALLERGAN HAS VIOLATED THE FALSE CLAIMS ACT

389. Allergan's off-label promotional schemes served their intended purpose by causing health care professionals to write off-label Vraylar prescriptions for non-medically accepted uses, which in turn caused the submission of false claims for reimbursement, resulting in hundreds of millions of dollars in improper payments by Government Programs.

390. Due in no small part to Allergan's illegal conduct, Vraylar has been heavily used for non-medically accepted uses by Government Program beneficiaries. Thus, Allergan's illegal conduct has caused Government Programs, to pay hundreds of millions of dollars that they should not have paid, unjustly enriching Allergan.

A. Allergan's Off-Label Promotion Caused the Submission of False Claims and Making of Materially False Statements to Government Programs

391. In order for a drug to be eligible for reimbursement by Medicare Part D, it must be, in relevant part, approved by the FDA and used for a "medically accepted indication."[122] A medically accepted indication is defined as any use that is FDA-approved or which is supported by one or more citations included or approved for inclusion in one of three specified drug compendia. Specific coverage policies and decisions are generally made by sponsors who contract with CMS to provide such coverage and are responsible for making coverage determinations in accordance with statutes and regulations.

392. In order for a drug to be eligible for reimbursement under the Medicaid program, the drug's manufacturer must first enter into a rebate agreement with HHS. Once a manufacturer has entered into a drug rebate agreement a state is generally required to cover the covered outpatient drugs of that manufacturer under the state plan unless "the prescribed used is not for a

[122] 42 U.S.C. § 1395w-102(d)(1) & (e)(4)(A)(ii).

medically accepted indication."[123] A medically accepted indication is any FDA-approved use or a use that is "supported by one or more citations included or approved for inclusion in any of the compendia" listed in the statute.[124] Thus, Medicaid does not cover off-label uses of drugs that are not supported by one or more citations included or approved for inclusion in the specified compendia.

393. Other Government Programs adhere to similar rules in determining a drug's eligibility for reimbursement and generally require that, in order to be covered, a drug must be prescribed for an FDA-approved use or a use supported in one or more drug compendia.

394. Allergan promoted Vraylar for uses that were neither approved by the FDA nor supported in any one of the applicable drug compendia, and as a result were ineligible for reimbursement by Government Programs including Medicare and Medicaid.

395. As a result of Allergan's off-label promotion of its drugs, health care professionals prescribed Allergan's drugs for these uses.

396. As a result of health care professionals' prescribing of Allergan's drugs, pharmacies filled prescriptions and submitted claims to Government Programs for Vraylar payments for these uses.

397. Because claims for payment of Vraylar were ineligible for reimbursement by Government Programs, these claims were false within the meaning the federal False Claims Act and State analogues.

398. Allergan's off-label promotion of Vraylar therefore caused the submission of claims that were false and not eligible for reimbursement by Government Programs.

[123] 42 U.S.C. § 1396r-8(d)(1)(B)(i).
[124] 42 U.S.C. § 1396r-8(k)(6).

399. Allergan engaged in this off-label promotion knowingly and with the intent to cause the submission of false claims to Government Programs.

400. Government Programs paid reimbursements for the resulting false claims, and as a result have incurred and continue to incur significant damages due to Allergan's off-label promotion.

401. By causing Vraylar claims that it knew were ineligible for reimbursement to be submitted to and paid for by Government Programs, Allergan also knowingly and intentionally made, used, or caused to be made or used, false records or statements material to false or fraudulent claims.

1. Submission of False Claims to Medicaid

402. The institutions and pharmacies where Allergan's drugs are filled agree to provide pharmaceuticals to the patients served by the *Qui Tam* States' Medicaid programs, and the *Qui Tam* States in turn reimburse these institutions and pharmacies for the cost of the Vraylar, plus a fixed dispensing fee meant to provide the dispenser with a profit for providing services to Medicaid patients.

403. The institutions and pharmacies submit their Medicaid claims for reimbursement by "batching them" daily, and submitting them electronically to the *Qui Tam* States. These claims include the claims for off-label prescriptions for the Allergan drugs. In instances in which claims were for off-label prescriptions, the institutions and pharmacies made false representations and false claims concerning Medicaid reimbursement directly to the *Qui Tam* States on a daily basis.

404. As part of each electronic claim, the institutions and pharmacies affix their unique Medicaid provider identification numbers, which serve as electronic stamps indicating that (as Medicaid providers) they are in compliance with all applicable federal and state laws.

405. The institutions and pharmacies are reimbursed on a monthly basis by the *Qui Tam* States for all approved claims.

406. The *Qui Tam* States are not financially responsible for paying 100% of the institutions' and pharmacies' claims for reimbursement. Medicaid is a joint federal-state program that provides healthcare benefits for certain groups, primarily low-income and disabled persons. The federal government provides matching funds and ensures that the states comply with minimum standards in the administration of the program. The federal share of states' Medicaid payments, known as the Federal Medical Assistance Percentage ("FMAP"), is based on each individual state's per capita income compared to the national average. Among the states, the FMAP is at least 50%, and in some instances, as high as 77%. For example, for fiscal year 2009, the federal share in Delaware was 50%; the federal share in Iowa was 62.62%.[125]

407. Through the FMAP process, State Medicaid administrators obtain the Federal Government's share of the pharmacies' reimbursements by submitting a quarterly Form 64 to CMS. For this reason, claims submitted to state Medicaid agencies, including those in the *Qui Tam* States, are presented to the Federal Government within the meaning of the FCA.

408. The Federal Government pays Medicaid claims through a continuing line of credit certified by the Secretary of the Treasury in favor of the state payee.[126] The Federal Government authorizes the state payee "to draw Federal funds as needed to pay the Federal share of

[125] *See* Office of the Assistance Secretary for Planning and Evaluation, *Federal Medical Assistance Percentages or Federal Financial Participation in State Assistance Expenditures FMAP, available at* http://aspe.hhs.gov/health/fmap.htm (last visited June 23, 2013).
[126] 42 C.F.R. § 430.30(d)(3), (4).

disbursements."[127] The state can draw down on those funds only to pay the Medicaid claims of healthcare providers.[128]

409. The funds made available to the state thus remain federal funds, in a Federal Reserve account, until they are drawn by the state and used to pay the institutions or pharmacies' claims.

410. The Federal Government also "approves" within the meaning of the FCA the claims submitted and paid through the Medicaid program. When a state presents its Form 64 (*i.e.,* the quarterly report of actual expenditures) to CMS, the amounts of any fraudulent claims the state paid will be included in those reports. Based on the information in the reports, CMS determines and approves whether the claims that the state paid with federal funds were appropriate. If CMS determines that certain claims paid by the state were improper, CMS may recoup the amount of the erroneously expended funds by reducing the amount of money provided to the state during the next quarter.

411. Because the Form 64 constitutes the United States' means for approving and paying the amount of federal funds expended by the state, these reports overstated the amount of federal funds to which the state was entitled by the amount fraudulently paid as a result of off-label prescriptions for the Allergan rugs. They were, therefore, false records or statements caused to be made or used to get false claims paid and approved by the United States.

412. The claims for reimbursement submitted by the health care professionals' offices and pharmacies to the *Qui Tam* States, which in turn caused the *Qui Tam* States to submit these

[127] 42 C.F.R. § 430.30(d)(3).
[128] 42 C.F.R. § 430.30(d).

claims for reimbursement to the Federal Government pursuant to FMAP, constituted false claims as a result of the claims for reimbursement for off-label prescriptions.

2. Submission of False Claims to Medicare Part D

413. The pharmacies where Vraylar are filled agree to provide pharmaceuticals to Medicare Part D Plans ("PDPs") for Medicare patients that they serve, and the PDPs in turn reimburse these pharmacies for the cost of the Allergan drugs, plus a fixed dispensing fee meant to provide the pharmacies with a profit for providing services to Medicare patients. PDPs (or MA-PDPs) are administered under contract with CMS by private entities such as Blue Cross Blue Shield plans, large commercial insurers such as Humana, and pharmacy benefit managers.

414. Every time a beneficiary fills a prescription covered under Part D, PDPs must submit a summary called the prescription drug event, or PDE record. The PDE record contains drug cost and payment data that enable CMS to administer the Part D benefit. CMS uses the PDE record to calculate reimbursement to PDPs for the cost of Vraylar, plus an amount meant to provide the PDPs with a profit for administering the PDP.

415. CMS reimbursement to PDPs pursuant to the PDE overstated the amount of federal funds to which PDPs were entitled by the amount fraudulently paid as a result of off-label prescriptions for Vraylar. They were, therefore, false records or statements caused to be made or used to get false claims paid and approved by the United States.

416. The claims for reimbursement of Vraylar submitted by the pharmacies to PDPs, which in turn caused the PDPs to submit these claims for reimbursement to the Federal Government, constituted false claims as a result of the claims for reimbursement for off-label prescriptions.

X. FRAUD AGAINST CALIFORNIA AND ILLINOIS COMMERCIAL PAYORS

A. The California Insurance Frauds Prevention Act (CIFPA)

417. The California Legislature enacted CIFPA to combat abusive practices aimed at defrauding private insurance providers. The legislature stated that it was specifically concerned with fraud on health insurance providers: "Health insurance fraud is a particular problem for health insurance policyholders. Although there are no precise figures, it is believed that fraudulent activities account for billions of dollars annually in added health care costs nationally. Health care fraud causes losses in premium dollars and increases health care costs unnecessarily."[129]

418. Cal. Ins. Code § 1871.7(a) prohibits the knowing employment of "runners, cappers, steerers or other persons to procure clients or patients . . . to perform or obtain services or benefits under a contract of insurance or that will be the basis for a claim against an insured individual or his or her insurer."

419. Pursuant to California Penal Code § 549, it is unlawful for any firm or corporations to "solicit[], accept[], or refer[] any business to or from any individual or entity with the knowledge that, or with reckless disregard for whether" that individual intends to make or cause to be made any false or fraudulent claim for payment of a health care benefit.

420. It is unlawful to "[k]nowingly prepare, make, or subscribe any writing, with the intent to present or use, or to allow it to be presented, in support of any false or fraudulent claim," or to aid, abet, solicit, or conspire with any person to do the same.[130]

[129] Cal. Ins. Code § 1871(h).
[130] Cal. Penal Code § 550(a)(5).

421. It is unlawful to "[k]nowingly make or cause to be made any false or fraudulent claim for payment of a health care benefit," or to aid, abet, solicit, or conspire with any person to do the same.[131]

422. It is unlawful to "[p]resent or cause to be presented any written or oral statement as part of, or in support of or opposition to, a claim for payment or other benefit pursuant to an insurance policy, knowing that the statement contains any false or misleading information concerning any material fact," or to knowingly assist or conspire with any person to do the same.[132]

423. It is unlawful to "[p]repare or make any written or oral statement that is intended to be presented to any insurer or any insurance claimant in connection with, or in support of or opposition to, any claim or payment or other benefit pursuant to an insurance policy, knowing that the statement contains any false or misleading information concerning any material fact," or to knowingly assist or conspire with any person to do the same.[133]

424. Through their fraudulent scheme, Allergan has violated the preceding provisions, making or causing fraudulent health care claims to be made to California commercial payors. By doing so, Allergan has substantially increased California commercial payors' costs and increased the costs of their participants' coverage.

B. The Illinois Insurance Claims Fraud Prevention Act (IICFPA)

425. The Illinois Legislature enacted the Illinois Insurance Claims Fraud Prevention Act (IICFPA) to combat abusive practices aimed at defrauding private insurance providers. The legislative findings and declarations make clear that it was specifically concerned with the social costs of fraud on private insurance providers, noting that the penalties in the IICFPA are "remedial"

[131] *Id.* § 550(a)(6).
[132] *Id.* § 550(b)(1).
[133] *Id.* § 550(b)(2).

and intended to achieve the "goals of disgorging unlawful profit, restitution, compensating the State for the costs of investigations and prosecution, and alleviating the social costs of increased insurance rates due to fraud."[134]

426. Under Illinois law, it is "unlawful to knowingly offer or pay any remuneration directly or indirectly, in cash or in kind, to induce any person to procure clients or patients to obtain services or benefits under a contract of insurance or that will be the basis for a claim against an insured person or the person's insurer."[135]

427. Under the Illinois Criminal Code of 2012, a "person commits insurance fraud when he or she knowingly obtains, attempts to obtain, or causes to be obtained, by deception, control over the property of an insurance company or self-insured entity by the making of a false claim or by causing a false claim to be made on any policy of insurance issued by an insurance company or by the making of a false claim or by causing a false claim to be made to a self-insured entity, intending to deprive an insurance company or self-insured entity permanently of the use and benefit of that property."[136]

428. The Illinois Criminal Code of 2012 sets forth that a "person commits health care benefits fraud against a provider, other than a governmental unit or agency, when he or she knowingly obtains or attempts to obtain, by deception, health care benefits and that obtaining or attempt to obtain health care benefits does not involve control over property of the provider."[137]

429. The Illinois Criminal Code of 2012 defines "aggravated insurance fraud" as 3 or more offenses within an 18-month period arising out of separate incidents or transactions.[138]

[134] 740 Ill. Comp. Stat. 92/5(c).
[135] 740 Ill. Comp. Stat. 92/5(a).
[136] 720 Ill. Comp. Stat. 5/17-10.5(a)(1).
[137] 720 Ill. Comp. Stat. 5/17-10.5(a)(2).
[138] 720 Ill. Comp. Stat. 5/17-10.5(b)(1).

430. The Illinois Criminal Code of 2012 further prohibits being an "organizer" of an aggravated insurance fraud, setting forth that a "person commits being an organizer of an aggravated insurance fraud on a private entity conspiracy if aggravated insurance fraud on a private entity forms the basis for a charge of conspiracy under Section 8-2 of this Code and the person occupies a position of organizer, supervisor, financer, or other position of management within the conspiracy."[139]

431. The Illinois Criminal Code of 2012 sets forth that:

> If aggravated insurance fraud on a private entity forms the basis for charges of conspiracy under Section 8-2 of this Code, the person or persons with whom the accused is alleged to have agreed to commit the 3 or more violations of this Section need not be the same person or persons for each violation, as long as the accused was part of the common scheme or plan to engage in each of the 3 or more alleged violations.[140]

432. Through their various schemes, described *infra*, Allergan has violated the preceding provisions, making or causing fraudulent health care claims to be made to Illinois commercial payors. By doing so, Allergan has substantially increased Illinois commercial payors' costs and in turn increased the costs of their participants' coverage.

XI. DEFENDANTS CAUSED THE PRESENTATION OF FALSE CLAIMS TO CALIFORNIA AND ILLINOIS INSURANCE PROVIDERS

433. Allergan's payments via sham speaker programs constitutes an illegal kickback scheme whereby Allergan provided prescribers with something of value (in the form of speaker fees), in return for or to induce purchasing, ordering, arranging for or recommending purchasing or ordering of Vraylar for which payment was made by California and Illinois commercial payors.

[139] 720 Ill. Comp. Stat. 5/17-10.5(b)(2).
[140] 720 Ill. Comp. Stat. 5/17-10.5(c).

434. These kickbacks caused physicians to prescribe Vraylar for on-label uses such as treatment of Bipolar Depression rather than cheaper competitor drugs. These kickbacks also caused physicians to prescribe Vraylar off-label such as for the unsafe and unapproved treatment of MDD.

435. These actions, in turn, caused health care providers to submit false or fraudulent claims for reimbursement to California and Illinois commercial payors.

436. Claims submitted to California and Illinois commercial payors where a kickback is involved in the underlying transaction are false within the meaning of the California Insurance Frauds Prevention Act and the Illinois Insurance Claims Fraud Prevention Act.

437. Claims that were submitted to California and Illinois commercial payors as a result, in part or in whole, based on kickbacks provided by Allergan were therefore false within the meaning of the California Insurance Frauds Prevention Act and the Illinois Insurance Claims Fraud Prevention Act.

438. Allergan's payment of kickbacks therefore caused the submission of claims that were false and not eligible for reimbursement to California and Illinois commercial payors.

439. Allergan's payment and offers of payment of kickbacks were made knowingly and with the intent to cause the submission of false claims to California and Illinois commercial payors.

440. California and Illinois commercial payors paid reimbursements for those false claims, and, as a result, have incurred and continue to incur significant damages due to Allergan's illegal payment of kickbacks.

XII. CAUSES OF ACTION

COUNT I
(Violation of False Claims Act, 31 U.S.C. § 3729(a)(1)(A))

441. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

442. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and are still presenting or causing to be presented, to the United States of America false or fraudulent claims for payment or approval of Vraylar, in violation of 31 U.S.C. § 3729(a)(1)(A).

443. Because of Defendants' actions, the United States of America has been, and continues to be, severely damaged.

COUNT II
(Violation of False Claims Act, 31 U.S.C. § 3729(a)(1)(B))

444. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

445. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and are still making, using or causing to be made or used, false records or statements material to the payment of false or fraudulent claims, in violation of 31 U.S.C. § 3729(a)(1)(B).

446. The United States of America, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements,

paid and continues to be paying or reimbursing for Vraylar prescribed to patients enrolled in Federal Programs.

447. Because of Defendants' actions, the United States of America has been, and continues to be, severely damaged.

COUNT III
(Violation of False Claims Act, 31 U.S.C. § 3729(a)(1)(C))

448. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

449. Defendants knowingly conspired, and are still conspiring, with the various health care professionals identified and described herein (as well as other unnamed co-conspirators) to commit acts in violation of 31 U.S.C. § 3729(a)(1)(A) & (a)(1)(B). Defendants and these health care professionals committed overt acts in furtherance of the conspiracy as described above.

450. Because of Defendants' actions, the United States of America has been and continues to be severely damaged.

COUNT IV
(Violation of False Claims Act, 31 U.S.C. § 3729(a)(1)(G))

451. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

452. Defendants knowingly avoided or decreased its obligation to pay or transmit money to the Government. Specifically, Defendants: (i) made, used, or caused to made or used, a record or statement to conceal, avoid, or decrease an obligation to the United States; (ii) the records or statements were in fact false; and (iii) Allergan knew that the records or statements were false.

453. Because of Defendants' actions, the United States of America has been and continues to be severely damaged.

COUNT V
(Violation of California False Claims Act)

454. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

455. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and are still presenting or causing to be presented, false or fraudulent claims for payment or approval in violation of Cal. Gov't Code § 12651(a)(1).

456. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and are still making, using, or causing to be made or used, false records or statements material to false or fraudulent claims, in violation of Cal. Gov't Code § 12651(a)(2).

457. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and are still making, using, or causing to be made or used, false records or statements to conceal, avoid or decrease an obligation to pay or transmit money to the State of California or its political subdivisions in violation of Cal. Gov't Code § 12651(a)(7).

458. The State of California, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims

and/or statements, paid, and continues to pay, for Vraylar prescriptions for recipients of state and state subdivision funded health insurance programs.

459. Because of Defendants' actions, the State of California, including its political subdivisions, has been and continues to be severely damaged.

COUNT VI
(Violation of Colorado Medicaid False Claims Act)

460. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

461. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented, or caused to be presented, and are still presenting or causing to be presented, to an officer or employee of the State of Colorado, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of Colo. Rev. Stat. § 25.5-4-305(a).

462. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and are still making, using, or causing to be made or used, false records or statements material to false or fraudulent claims, in violation of Colo. Rev. Stat. § 25.5-4-305(b).

463. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and are still making, using, or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit

money to the State of Colorado, or its political subdivisions, in violation of Colo. Rev. Stat. § 25.5-4-305(f).

464. The State of Colorado, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and continue to pay, for Vraylar prescriptions for recipients of state and state subdivision funded health insurance programs.

465. Because of Defendants' actions, the State of Colorado and/or its political subdivisions have been and continues to be severely damaged.

COUNT VII
(Violation of Connecticut False Claims Act for Medical Assistance Programs)

466. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

467. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, presented, or caused to be presented to, and are still presenting or causing to be presented to, an officer or employee of the State of Connecticut or its political subdivisions false or fraudulent claims for payment, in violation of Conn. Gen. Stat. § 4-275(a)(1).

468. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and are still making, using, or causing to be made or used, false records or statements to get false or fraudulent claims paid in violation of Conn. Gen. Stat. § 4-275(a)(2).

469. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and are still making, using, or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Connecticut or its political subdivisions in violation of Conn. Gen. Stat. § 4-275(a)(7).

470. The State of Connecticut, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid and continue to pay for Vraylar prescriptions for recipients of state and state subdivision funded health insurance programs.

471. Because of Defendants' actions, the State of Connecticut and/or its political subdivisions have been and continue to be severely damaged.

COUNT VIII
(Violation of Delaware False Claims and Reporting Act)

472. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

473. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and are still presenting or causing to be presented, to an officer or employee of the State of Delaware, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of Del. Code Ann. tit. 6, §1201(a)(1).

474. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly

made, used, or caused to be made or used, and are still making, using, or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the State of Delaware, or its political subdivisions, in violation of Del. Code Ann. tit. 6, §1201(a)(2).

475. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and are still making, using, or causing to be made or used, false records or statements to conceal, avoid, increase or decrease an obligation to pay or transmit money to the State of Delaware, or its political subdivisions, in violation of Del. Code Ann. tit. 6, § 120l(a)(7).

476. The State of the State of Delaware, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid and continue to pay for Vraylar prescriptions for recipients of health care programs funded by the State of Delaware.

477. Because of Defendants' actions, the State of Delaware and/or its political subdivisions have been and continue to be severely damaged.

COUNT IX
(Violation of District of Columbia False Claims Act)

478. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

479. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented, or caused to be presented, and are still presenting or causing to be presented, to an

officer or employee of the District, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of D.C. Code § 2-381.02(a)(l).

480. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be used, and are still making, using, or causing to be made or used, false records or statements to get false claims paid or approved by the District, or its political subdivisions, in violation of D.C. Code § 2-381.02(a)(2).

481. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and are still making, using, or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the District, or its political subdivisions, in violation of D.C. Code § 2-381.02(a)(6).

482. The District of Columbia, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance upon the accuracy of these claims and/or statements, paid and continue to pay for Vraylar prescriptions for recipients of health insurance programs funded by the District.

483. Because of Defendants' actions, the District of Columbia and/or its political subdivisions have been and continue to be severely damaged.

COUNT X
(Violation of Florida False Claims Act)

484. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

485. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and are still presenting or causing to be presented, to an officer or employee of the State of Florida, or its agencies, false or fraudulent claims for payment or approval, in violation of Fla. Stat. § 68.082(2)(a).

486. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and are still making, using, or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the State of Florida, or its agencies, in violation of Fla. Stat. § 68.082(2)(b).

487. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and are still making, using, or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Florida, or its agencies, in violation of Fla. Stat. § 68.082(2)(g).

488. The State of Florida, or its agencies, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid and continue to pay for Vraylar prescriptions for recipients of health insurance plans funded by the State of Florida or its agencies.

489. Because of Defendants' actions, the State of Florida and/or its agencies have been and continue to be severely damaged.

COUNT XI
(Violation of Georgia False Medicaid Claims Act)

490. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

491. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and are still presenting or causing to be presented, to the Georgia Medicaid program false or fraudulent claims for payment or approval, in violation of Ga. Code Ann. § 49-4-168.1(a)(1).

492. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and are still making, using, or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the Georgia Medicaid program, in violation of Ga. Code Ann. § 49-4-168.1(a)(2).

493. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and are still making, using, or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Georgia, or its political subdivisions, in violation of Ga. Code Ann. § 49-4-168.1(a)(7).

494. The State of Georgia, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid and continue to pay for Vraylar prescriptions for recipients of Medicaid.

495. Because of Defendants' actions, the State of Georgia and/or political subdivisions have been and continue to be severely damaged.

COUNT XII
(Violation of Hawaii False Claims Act)

496. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

497. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and are still presenting or causing to be presented, to an officer or employee of the State of Hawaii, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of Haw. Rev. Stat. § 661-21(a)(l).

498. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made and used, and are still making, using, or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the State of Hawaii, or its political subdivisions, in violation of Haw. Rev. Stat. § 661-21(a)(2).

499. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and are still making, using, or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Hawaii, or its political subdivisions, in violation of Haw. Rev. Stat. § 661-21(a)(7).

500. The State of Hawaii, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance upon the accuracy of these claims and/or statements, paid and continue to pay for Vraylar prescriptions for recipients of state funded health insurance programs.

501. Because of Defendants' actions, the State of Hawaii and/or its political subdivisions have been and continue to be severely damaged.

COUNT XIII
(Violation of Illinois False Claims Act)

502. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

503. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and are still presenting or causing to be presented, false or fraudulent claims for payment or approval, in violation of 740 Ill. Comp. Stat. 175/3(a)(1)(A).

504. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and are still making, using, or causing to be made or used, false records or statements material to get false or fraudulent claims paid or approved by the State of Illinois, or its political subdivisions, in violation of 740 Ill. Comp. Stat. 175/3(a)(1)(B).

505. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and are still making, using, or causing to be made or used, false records or statements material to conceal, avoid or decrease an obligation to pay or

transmit money to the State of Illinois, or its political subdivisions, in violation of 740 Ill. Comp. Stat. 175/3(a)(1)(G).

506. The State of Illinois, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of those claims and/or statements, paid and continue to pay for Vraylar prescriptions for recipients of state funded health insurance programs.

507. Because of Defendants' actions, the State of Illinois and/or its political subdivisions have been and continue to be severely damaged.

COUNT XIV
(Violation of Indiana False Claims and Whistleblower Protection Act)

508. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

509. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally presented, or caused to be presented, and are still presenting or causing to be presented, false claims to the State of Indiana, or its political subdivisions, for payment or approval, in violation of Ind. Code § 5-11-5.5-2(b)(l).

510. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made, used, or caused to be made or used, and are still making, using, or causing to be made or used, false records or statements to obtain payment or approval of false claims from the State of Indiana, or its political subdivisions, in violation of Ind. Code § 5-11-5.5-2(b)(2).

511. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made, used, or caused to be made or used, and are still making, using, or causing to be made or used, false records or statements to avoid an obligation to pay or transmit money to the State of Indiana, or its political subdivisions, in violation of Ind. Code § 5-11-5.5-2(b)(6).

512. The State of Indiana, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of those claims and/or statements, paid and continue to pay for Vraylar prescriptions for recipients of state funded health insurance programs.

513. Because of Defendants' actions, the State of Indiana and/or its political subdivisions have been and continue to be severely damaged.

COUNT XV
(Violation of Iowa False Claims Act)

514. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

515. Defendants, in reckless disregard or deliberate ignorance for the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented, or caused to be presented, and are still presenting or causing to be presented, false or fraudulent claims for payment or approval, in violation of Iowa Code § 685.2(1)(a).

516. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and are still making, using, or causing to be made or

used, false records or statements material to false or fraudulent claims, in violation of Iowa Code § 685.2(1)(b).

517. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and are still making, using, or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Iowa, or its political subdivisions, in violation of Iowa Code § 685.2(1)(g).

518. The State of Iowa, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid for Vraylar prescriptions for recipients of health insurance programs funded by the state or its political subdivisions.

519. Because of Defendants' actions, the State of Iowa and/or its political subdivisions have been and continue to be severely damaged.

COUNT XVI
(Violation of Louisiana Medical Assistance Programs Integrity Law)

520. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

521. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented, or caused to be presented, and are still presenting or causing to be presented, false or fraudulent claims, in violation of La. Rev. Stat. Ann. § 46:438.3(A).

522. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly

engaged in misrepresentation, and are still engaging in misrepresentation, to obtain, or attempt to obtain, payment from medical assistance programs funds, in violation of La. Rev. Stat. Ann. § 46:438.3(B).

523. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly submitted, and may continue to submit, claims for goods, services or supplies which were medically unnecessary or which were of substandard quality or quantity, in violation of La. Rev. Stat. Ann. § 46:438.3(D).

524. The State of Louisiana, its medical assistance programs, political subdivisions, and/or the Department, unaware of the falsity of the claims and/or statements made by Defendants, or their actions as set forth above, acted in reliance, and may continue to act in reliance, on the accuracy of Defendants' claims and/or statements in paying for Vraylar prescriptions for medical assistance program recipients.

525. Because of Defendants' actions, as set forth above, the State of Louisiana, its medical assistance programs, political subdivisions, and/or the Department have been and continue to be severely damaged.

COUNT XVII
(Violation of Maryland False Health Claims Act)

526. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

527. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and are still presenting or causing to be presented, false or

fraudulent claims for payment or approval, in violation of Md. Code Ann., Health-Gen. § 2-602(a)(1).

528. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and are still making, using, or causing to be made or used, false records or statements material to false or fraudulent claims, in violation of Md. Code Ann., Health-Gen. § 2-602(a)(2).

529. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and are still making, using, or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Maryland, or its political subdivisions, in violation of Md. Code Ann., Health-Gen. § 2-602(a)(8).

530. The State of Maryland, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid for Vraylar prescriptions for recipients of health insurance programs funded by the state or its political subdivisions.

531. Because of Defendants' actions, the State of Maryland and/or its political subdivisions have been and continue to be severely damaged.

COUNT XVIII
(Violation of Massachusetts False Claims Act)

532. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

533. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and are still presenting or causing to be presented, false or fraudulent claims for payment or approval, in violation of Mass. Gen. Laws ch. 12 § 5B(1).

534. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and are still making, using, or causing to be made or used, false records or statements to obtain payment or approval of claims by the Commonwealth of Massachusetts, or its political subdivisions, in violation of Mass. Gen. Laws ch. 12 § 5B(2).

535. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and are still making, using, or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the Commonwealth of Massachusetts, or its political subdivisions, in violation of Mass. Gen. Laws ch. 12 § 5B(8).

536. The Commonwealth of Massachusetts, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid and continue to pay for Vraylar prescriptions for recipients of health insurance programs funded by the state or its political subdivisions.

537. Because of Defendants' actions, the Commonwealth of Massachusetts and/or its political subdivisions have been and continue to be severely damaged.

COUNT XIX
(Violation of Michigan Medicaid False Claims Act)

538. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

539. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made or caused to be made, and are still making or causing to be made, false statements or false representations of material facts in an application for Medicaid benefits, in violation of Mich. Comp. Laws § 400.603(1).

540. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made or caused to be made false statements or false representations of a material fact for use in determining rights to a Medicaid benefit, in violation of Mich. Comp. Laws § 400.603(2).

541. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly concealed or failed to disclose, and are still concealing or failing to disclose, an event affecting its initial or continued right to receive a Medicaid benefit, or the initial or continued right of any other person on whose behalf Defendants has applied for or is receiving a benefit with intent to obtain a benefit to which Defendants were not entitled or in an amount greater than that to which Defendants were entitled, in violation of Mich. Comp. Laws § 400.603(3).

542. Defendants, in possession of facts under which they are aware or should be aware of the nature of their conduct and that their conduct is substantially certain to cause the payment of a Medicaid benefit, knowingly made, presented, or caused to be made or presented, and are still

making, presenting, or causing to be presented, to an employee or officer of the State of Michigan, or its political subdivisions, false claims under the Social Welfare Act, Mich. Comp. Laws §§ 400.1-400.122, in violation of Mich. Comp. Laws § 400.607(1).

543. The State of Michigan, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid and continue to pay for Vraylar prescriptions for recipients of Medicaid.

544. Because of Defendants' actions, the State of Michigan and/or its political subdivisions have been and continue to be severely damaged.

COUNT XX
(Violation of Minnesota False Claims Act)

545. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

546. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and are still presenting or causing to be presented, to an officer or employee of the State of Minnesota, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of Minn. Stat. § 15C.02(a)(1).

547. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and are still making, using, or causing to be made or used, false records or statements to get false or fraudulent claim paid or approved by the State of Minnesota, or its political subdivisions, in violation of Minn. Stat. § 15C.02(a)(2).

548. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and are still making, using, or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Minnesota, or its political subdivisions, in violation of Minn. Stat. § 15C.02(a)(7).

549. The State of Minnesota, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid and continue to pay for Vraylar prescriptions for recipients of state and state subdivision funded health insurance programs.

550. Because of Defendants' actions, the State of Minnesota and/or its political subdivisions have been and continue to be severely damaged.

COUNT XXI
(Violation of Montana False Claims Act)

551. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

552. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and are still presenting or causing to be presented, to an officer or employee of the State of Montana, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of Mont. Code Ann. § 17-8-403(1)(a).

553. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly

made, used, or caused to be made or used, and are still making, using, or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the State of Montana, or its political subdivisions, in violation of Mont. Code Ann. § 17-8-403(1)(b).

554. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and are still making, using, or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Montana, or its political subdivisions, in violation of Mont. Code Ann. § 17-8-403(1)(g).

555. The State of Montana, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid and continue to pay for Vraylar prescriptions for recipients of health insurance programs funded by the state or its political subdivisions.

556. Because of Defendants' actions, the State of Montana and/or its political subdivisions have been and continue to be severely damaged.

COUNT XXII
(Violation of Nevada False Claims Act)

557. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

558. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and are still presenting or causing to be presented, false claims for payment or approval, in violation of Nev. Rev. Stat. § 357.040(1)(a).

559. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and are still making, using, or causing to be made or used, false records or statements to obtain payment or approval of false claims, in violation of Nev. Rev. Stat. § 357.040(1)(b).

560. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and are still making, using, or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Nevada, or its political subdivisions, in violation of Nev. Rev. Stat. § 357.040(1)(g).

561. The State of Nevada, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid and continue to pay for Vraylar prescriptions for recipients of health insurance programs funded by the state or its political subdivisions.

562. Because of Defendants' actions, the State of Nevada and/or its political subdivisions have been and continue to be severely damaged.

COUNT XXIII
(Violation of New Jersey False Claims Act)

563. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

564. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or

intentionally presented or caused to be presented, and are still presenting or causing to be presented, to an employee, officer, or agent of the State of New Jersey, or to any contractor, grantee, or other recipient of State funds, false or fraudulent claims for payment or approval, in violation of N.J. Stat. Ann. § 2A:32C-3(a).

565. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to made or used, and are still making, using, or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the State of New Jersey, or its political subdivisions, in violation of N.J. Stat. Ann. § 2A:32C-3(b).

566. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and are still making, using, or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of New Jersey, or its political subdivisions, in violation of N.J. Stat. Ann. § 2A:32C-3(g).

567. The State of New Jersey, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid and continue to pay for Vraylar prescriptions for recipients of Medicaid.

568. Because of Defendants' actions, as set forth above, the State of New Jersey and/or its political subdivisions have been and continue to be severely damaged.

COUNT XXIV
(Violation of New Mexico Medicaid False Claims Act and Fraud Against Taxpayers Act)

569. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

570. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and are still presenting or causing to be presented, to the State of New Mexico, or its political subdivisions, false or fraudulent claims for payment under the Medicaid program, in violation of N.M. Stat. Ann. § 27-14-4(A) and N.M. Stat. Ann. § 44-9-3(A)(1).

571. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and are still making, using, or causing to be made or used, false records or statements to obtain false or fraudulent claims under the Medicaid program paid for or approved by the State of New Mexico, or its political subdivisions, in violation of N.M. Stat. Ann. § 27-14-4(C) and N.M. Stat. Ann. § 44-9-3(A)(2).

572. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and are still making, using, or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of New Mexico, or its political subdivisions, relative to the Medicaid program, in violation of N.M. Stat. Ann. § 27-14-4(E) and N.M. Stat. Ann. § 44-9-3(A)(8).

573. The State of New Mexico, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs for recipients of health insurance programs funded by the state or its political subdivisions.

574. Because of Defendants' actions, as set forth above, the State of New Mexico and/or its political subdivisions have been and continue to be severely damaged.

COUNT XXV
(Violation of New York False Claim Act)

575. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

576. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and are still presenting or causing to be presented, false or fraudulent claims for payment or approval, in violation of N.Y. State Fin. Law § 189(1)(a).

577. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and are still making, using, or causing to be made or used, false records or statements material to false or fraudulent claims, in violation of N.Y. State Fin. Law § 189(1)(b).

578. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and are still making, using, or causing to be made or

used, false records or statements material to an obligation to pay or transmit money to the State of New York, or its political subdivisions, in violation of N.Y. State Fin. Law § 189(1)(g).

579. The State of New York, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid and continue to pay for Vraylar prescriptions for recipients of health insurance programs funded by the state or its political subdivisions.

580. Because of Defendants' actions, set forth above, the State of New York and/or its political subdivisions have been and continue to be severely damaged.

COUNT XXVI
(Violation of North Carolina False Claims Act)

581. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

582. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and are still presenting or causing to be presented, false or fraudulent claims for payment or approval, in violation of N.C. Gen. Stat. § 1-607(a)(1).

583. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and are still making, using, or causing to be made or used, false records or statements material to false or fraudulent claims, in violation of N.C. Gen. Stat. § 1-607(a)(2).

584. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly

made, used, or caused to be made or used, and are still making, using, or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of North Carolina, or its political subdivisions, in violation of N.C. Gen. Stat. § 1-607(a)(7).

585. The State of North Carolina, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid and continue to pay for Vraylar prescriptions for recipients of health insurance programs funded by the state or its political subdivisions.

586. Because of Defendants' actions, as set forth above, the State of North Carolina and/or its political subdivisions have been and continue to be severely damaged.

COUNT XXVII
(Violation of Oklahoma Medicaid False Claims Act)

587. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

588. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and are still presenting or causing to be presented, to an officer or employee of the State of Oklahoma, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of Okla. Stat. tit. 63, § 5053.1(B)(1).

589. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made or caused to be made, and are still making or causing to be made, false records or statements

to get false or fraudulent claims paid or approved by the State of Oklahoma, or its political subdivisions, in violation of Okla. Stat. tit. 63, § 5053.1(B)(2).

590. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and are still making, using, or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Oklahoma, or its political subdivisions, in violation of Okla. Stat. tit. 63, § 5053.1(B)(7).

591. The State of Oklahoma, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid and continue to pay for Vraylar prescriptions for recipients of Medicaid.

592. Because of Defendants' actions, as set forth above, the State of Oklahoma and/or its political subdivisions have been and continue to be severely damaged.

COUNT XXVIII
(Violation of Rhode Island False Claims Act)

593. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

594. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and are still presenting or causing to be presented, to an officer or employee of the State of Rhode Island or a member of Rhode Island's National Guard, false or fraudulent claims for payment or approval, in violation of R.I. Gen. Laws § 9-1.1-3(a)(1).

595. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made or caused to be made, and are still making or causing to be made, false records or statements to get false or fraudulent claims paid or approved by the State of Rhode Island, or its political subdivisions, in violation of R.I. Gen. Laws § 9-1.1-3(a)(2).

596. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and are still making, using, or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Rhode Island, or its political subdivisions, in violation of R.I. Gen. Laws § 9-1.1-3(a)(7).

597. The State of Rhode Island, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid and continue to pay for Vraylar prescriptions for recipients of Medicaid.

598. Because of Defendants' actions, as set forth above, the State of Rhode Island and/or its political subdivisions have been and continue to be severely damaged.

COUNT XXIX
(Violation of Tennessee Medicaid False Claims Act)

599. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

600. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and are still presenting or causing to be presented, to the State

of Tennessee, or its political subdivisions, false or fraudulent claims for payment under the Medicaid program, in violation of Tenn. Code Ann. § 71-5-182(a)(1)(A).

601. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and are still making, using, or causing to be made or used, false or fraudulent records or statements to get false or fraudulent claims under the Medicaid program paid for or approved by the State of Tennessee, or its political subdivisions, in violation of Tenn. Code Ann. § 71-5-182(a)(1)(B).

602. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and are still making, using, or causing to be made or used, false or fraudulent records or statements to conceal, avoid or decrease an obligation to pay or transmit money to the State of Tennessee, or its political subdivisions, relative to the Medicaid program, in violation of Tenn. Code Ann. § 71-5-182(a)(1)(D).

603. The State of Tennessee, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid and continue to pay for Vraylar prescriptions for recipients of the Medicaid program.

604. Because of Defendants' actions, as set forth above, the State of Tennessee and/or its political subdivisions have been and continue to be severely damaged.

COUNT XXX
(Violation of Texas Medical Assistance Program, Damages, and Penalties Act)

605. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

606. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made or caused to be made, and are still making or causing to be made, false statements or misrepresentations of material fact that permitted Defendants to receive a benefit or payment under the Medicaid program that was not authorized or that was greater than the benefit or payment that was authorized, in violation of Tex. Hum. Res. Code Ann. § 36.002(1).

607. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly concealed or failed to disclose, or caused to be concealed or not disclosed—and are still concealing or failing to disclose, or causing to be concealed or not disclosed—information that permitted Defendants to receive a benefit or payment under the Medicaid program that was not authorized or that was greater than the payment that was authorized, in violation of Tex. Hum. Res. Code Ann. § 36.002(2).

608. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, caused to be made, induced, or sought to induce, and are still making, causing to be made, inducing, or seeking to induce, false statements or misrepresentations of material fact concerning information required to be provided by a federal or state law, rule, regulation or provider agreement pertaining to the Medicaid program, in violation of Tex. Hum. Res. Code Ann. § 36.002(4)(B).

609. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, and are still making, claims under the Medicaid program for products that were inappropriate, in violation of Tex. Hum. Res. Code Ann. § 36.002(7)(C).

610. The State of Texas, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs for recipients of Medicaid.

611. Because of Defendants' actions, as set forth above, the State of Texas and/or its political subdivisions have been and continue to be severely damaged.

COUNT XXXI
(Violation of Vermont False Claims Act)

612. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

613. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made or caused to be made, and are still making or causing to be made, false statements or misrepresentations of material fact that permitted Defendants to receive a benefit or payment under the Medicaid program that was not authorized or that was greater than the benefit or payment that was authorized, in violation of Vt. Stat. Ann. tit. 32, § 631(a)(1)-(2).

614. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly concealed or failed to disclose, or caused to be concealed or not disclosed—and are still concealing or failing to disclose, or causing to be concealed or not disclosed—information that permitted

Defendants to receive a benefit or payment under the Medicaid program that was not authorized or that was greater than the payment that was authorized, in violation of Vt. Stat. Ann. tit. 32, § 631(a).

615. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, caused to be made, induced, or sought to induce, and are still making, causing to be made, inducing, or seeking to induce, false statements or misrepresentations of material fact concerning information required to be provided by a federal or state law, rule, regulation or provider agreement pertaining to the Medicaid program, in violation of Vt. Stat. Ann. tit. 32, § 631(a)(2).

616. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, and are still making, claims under the Medicaid program for products that were inappropriate, in violation of Vt. Stat. Ann. tit. 32, § 631(a).

617. The State of Vermont, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs for recipients of Medicaid.

618. Because of Defendants' actions, as set forth above, the State of Vermont and/or its political subdivisions have been and continue to be severely damaged.

COUNT XXXII
(Violation of Virginia Fraud Against Taxpayers Act)

619. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

620. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and are still presenting or causing to be presented, to an officer or employee of the Commonwealth of Virginia, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of Va. Code Ann. § 8.01-216.3(A)(1).

621. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and are still making, using, or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the Commonwealth of Virginia, or its political subdivisions, in violation of Va. Code Ann. § 8.01-216.3(A)(2).

622. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and are still making, using, or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the Commonwealth of Virginia, or its political subdivisions, in violation of Va. Code Ann. § 8.01-216.3(A)(7).

623. The Commonwealth of Virginia, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance upon the accuracy of these claims and/or statements, paid and continue to pay for Vraylar prescriptions for recipients of state funded health insurance programs.

624. Because of Defendants' actions, as set forth above, the Commonwealth of Virginia and/or its political subdivisions have been and continue to be severely damaged.

COUNT XXXIII
(Violation of Washington Medicaid False Claims Act)

625. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

626. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and are still presenting or causing to be presented, false or fraudulent claims for payment of approval, in violation of Wash. Rev. Code § 74.66.020(1)(a).

627. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and are still making, using, or causing to be made or used, false records or statements material to false or fraudulent claims, in violation of Wash. Rev. Code § 74.66.020(1)(b).

628. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and are still making, using, or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Washington, or its political subdivisions, in violation of Wash. Rev. Code § 74.66.020(1)(g).

629. The State of Washington, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance upon the accuracy of these claims and/or statements, paid and continue to pay for Vraylar prescriptions for recipients of state funded health insurance programs.

630. Because of Defendants' actions, as set forth above, the State of Washington and/or its political subdivisions have been and continue to be severely damaged.

COUNT XXXIV
(Violation of Puerto Rico False Claims Act)

631. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

632. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and are still presenting or causing to be presented, false or fraudulent claims for payment of approval, in violation of 2018 P.R. Act 154 (H.B. 1627), § 3.07(A)(1).

633. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and are still making, using, or causing to be made or used, false records or statements material to false or fraudulent claims, in violation of 2018 P.R. Act 154 (H.B. 1627), § 3.07(A)(2).

634. The Commonwealth of Puerto Rico, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance upon the accuracy of these claims and/or statements, paid, and continues to pay, for Vraylar prescriptions for recipients of Commonwealth-funded health insurance programs.

635. Because of Defendants' actions, as set forth above, the Commonwealth of Puerto Rico and/or its political subdivisions have been and continue to be severely damaged.

COUNT XXXV
(Violation of Chicago False Claims Ordinance)

636. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

637. By virtue of the above-described acts, Defendants knowingly and willfully promoted Vraylar for unapproved and unsafe uses.

638. By virtue of the above-described acts, Defendants knowingly made or caused to be made false claims for Defendants' drugs to the Chicago City Government.

639. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Chicago City Government to approve and pay such false and fraudulent claims.

640. The Chicago City Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

641. By reason of the Defendants' unlawful acts, the City of Chicago has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

COUNT XXXVI
(Violation of Hallandale Beach False Claims Ordinance)

642. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

643. By virtue of the above-described acts, Defendants knowingly and willfully promoted Vraylar for unapproved and unsafe uses.

644. By virtue of the above-described acts, Defendants knowingly made or caused to be made false claims for Defendants' drugs to the Hallandale Beach City Government.

645. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Hallandale Beach City Government to approve and pay such false and fraudulent claims.

646. The Hallandale Beach City Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

647. By reason of the Defendants' unlawful acts, the City of Hallandale Beach has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

COUNT XXXVII
(Violation of Broward County False Claims Ordinance)

648. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

649. By virtue of the above-described acts, Defendants knowingly and willfully promoted Vraylar for unapproved and unsafe uses.

650. By virtue of the above-described acts, Defendants knowingly made or caused to be made false claims for Defendants' drugs to the Broward County Government.

651. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Broward County Government to approve and pay such false and fraudulent claims.

652. The Broward County Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

653. By reason of the Defendants' unlawful acts, Broward County has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

COUNT XXXVIII
(Violation of Miami-Dade False Claims Ordinance)

654. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

655. By virtue of the above-described acts, Defendants knowingly and willfully promoted Vraylar for unapproved and unsafe uses.

656. By virtue of the above-described acts, Defendants knowingly made or caused to be made false claims for Defendants' drugs to the Miami-Dade County Government.

657. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Miami-Dade County Government to approve and pay such false and fraudulent claims.

658. The Miami-Dade County Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

659. By reason of the Defendants' unlawful acts, Miami-Dade County has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

COUNT XXXIX
(Violation of CIFPA)

660. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

661. Defendants knowingly employed physicians as "runners, cappers, steerers, or other persons" by paying them kickbacks to "procure clients or patients to perform or obtain services or benefits under a contract of insurance," in violation of Cal. Ins. Code § 1871.7(a) and Cal. Bus. & Prof. Code § 650(a).

662. Defendants also knowingly employed its sales representatives as "runners, cappers, steerers, or other persons" to cause health care professionals and their staff to be paid kickbacks, and/or to falsify or cause said professionals and staff to falsify health care claims, all to "procure clients or patients to perform or obtain services or benefits under a contract of insurance," and all in violation of Cal. Ins. Code § 1871.7(a) and Cal. Bus. & Prof. Code § 650(a).

663. Through their payment of kickbacks, Defendants knowingly prepared, made, and/or subscribed a writing, with the intent to present or use it, or to allow it to be presented, in support of false and/or fraudulent claims, in violation of Cal. Ins. Code § 1871.7(b) and Cal. Penal Code § 550(a)(5).

664. Through their payment and receipts of kickbacks, Defendants knowingly made or caused to be made false or fraudulent claims for the payment of a health care benefit, in violation of Cal. Ins. Code § 1871.7(b) and Cal. Penal Code § 550(a)(6).

665. Through their payment and/or receipt of kickbacks, Defendants presented or caused to be presented written and/or oral statements as part of, or in support of, claims for payment or other benefit pursuant to an insurance policy, knowing that the statements contained false and/or

misleading information concerning one or more material facts, in violation of Cal. Ins. Code § 1871.7(b) and Cal. Penal Code § 550(b)(1).

666. Through their payment and/or receipt of kickbacks, Defendants prepared or made written and/or oral statements that were intended to be represented to an insurer or insurance claimant in connection with, or in support of, claims for payment or other benefits pursuant to an insurance policy, knowing that the statements contained false or misleading information concerning one or more material facts, in violation of Cal. Ins. Code § 1871.7(b) and Cal. Penal Code § 550(b)(2).

667. The payment and/or receipt of kickbacks as described herein has had the direct effect of significantly increasing the number of claims submitted to and paid by California insurers for Vraylar prescriptions, thereby increasing the amount of money spent by California insurers for this drug.

668. Defendants' payments of kickbacks induced the cooperation of physicians to evade California insurers' cost containment programs, and thereby aided and/or abetted Defendants' scheme to induce the dispensing of Vraylar. This use of kickbacks has had the direct effect of significantly increasing the number of Vraylar prescriptions, thereby increasing the price of said prescriptions, which were then paid for or reimbursed by California insurers.

COUNT XXXX
(Violation of IICFPA)

669. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

670. Defendants violated the Illinois Criminal Code and the IICFPA by committing "insurance fraud" through payment of kickbacks and/or falsification of, or causing the falsification

of, prior authorization requests and/or health care claims, and/or presenting or causing to be presented written and/or oral statements as part of, or in support of, claims for payment or other benefit pursuant to an insurance policy, knowing that the claims and/or statements contained false and/or misleading information concerning one or more material facts. Defendants knowingly prepared, made, and/or subscribed a writing, with the intent to present or use it, or to allow it to be presented, in support of false and/or fraudulent claims. The foregoing actions were all in violation of 740 Ill. Comp. Stat. 92/5(a)-(b), the Illinois Criminal Code of 2012 (720 Ill. Comp. Stat. 17-8.10.5(a)(1)), and the Illinois Criminal Code of 1961 (720 Ill. Comp. Stat. 5/46-1(a)) (effective January 1, 2006 through June 30, 2011).

671. Defendants further violated the Illinois Criminal Code and the IICFPA by committing "health care benefits fraud" through payment of kickbacks and/or falsification of, or causing the falsification of, prior authorization requests and/or health care claims, and/or presenting or causing to be presented written and/or oral statements as part of, or in support of, claims for payment or other benefit pursuant to an insurance policy, knowing that the claims and/or statements contained false and/or misleading information concerning one or more material facts. Defendants also knowingly made or caused to be made false or fraudulent claims for the payment of a health care benefit. The foregoing actions were all in violation of 740 Ill. Comp. Stat. 92/5(b) and the Illinois Criminal Code of 2012 (720 Ill. Comp. Stat. 5/17-8.10.5(a)(2)).

672. Defendants' violations of the IICFPA were "aggravated" offenses because Defendants caused 3 or more violations within 18 months, all in violation of 740 Ill. Comp. Stat. § 92/5(b), the Illinois Criminal Code of 2012 (720 Ill. Comp. Stat. 5/17-8.10.5(b)(1)), and the Illinois Criminal Code of 1961 (720 Ill. Comp. Stat. 5/46-2) (effective January 1, 2006 through June 30, 2011).

673. Defendants' violations of the IICFPA were in the nature of a "conspiracy" or "conspiracies" with other persons and/or entities, all in violation of 740 Ill. Comp. Stat. 92/5(b), the Illinois Criminal Code of 2012 (720 Ill. Comp. Stat. 5/17-8.10.5(c)), and the Illinois Criminal Code of 1961 (720 Ill. Comp. Stat. 5/46-3) (effective January 1, 2006 through June 30, 2011).

674. Defendants were the "organizer[s]" of the conspiracy or conspiracies with other persons and/or entities, all in violation of 740 Ill. Comp. Stat. 92/5(b), the Illinois Criminal Code of 2012 (720 Ill. Comp. Stat. 5/17-8.10.5(b)(2)), and the Illinois Criminal Code of 1961 (720 Ill. Comp. Stat. 5/46-4) (effective January 1, 2006 through June 30, 2011).

675. Defendants' payments of kickbacks induced the cooperation of health care providers to evade Illinois insurers' cost containment programs, and thereby aided and/or abetted Allergan's scheme to induce the dispensing of Vraylar.

676. The payment and/or receipt of kickbacks as described herein has had the direct effect of greatly increasing the number of claims submitted to and paid by Illinois commercial payors for Vraylar, thereby increasing the amount of money spent by these entities for these drugs.

XIII. PRAYER FOR RELIEF

WHEREFORE, Relator prays for judgment against Defendants as follows:

A. That Defendants be ordered to cease and desist from submitting any more false claims, or further violating 31 U.S.C. §§ 3729 *et seq.*; Cal. Gov't Code §§ 12650 *et seq.*; Colo. Rev. Stat. §§ 25.5-4-304 *et seq.*; Conn. Gen. Stat. §§ 4-274 *et seq.*; Del. Code Ann. tit. 6, §§ 1201 *et seq.*; D.C. Code §§ 2-381.01 *et seq.*; Fla. Stat. §§ 68.081 *et seq.*; Ga. Code Ann. §§ 49-4-168 *et seq.*; Haw. Rev. Stat. §§ 661-21 *et seq.*; 740 Ill. Comp. Stat. §§ 175/1 *et seq.*; Ind. Code §§ 5-11-5.7 *et seq.*; Iowa Code tit. 15 §§ 685.1 *et seq.*; La. Rev. Stat. Ann. §§ 46:437.1 *et seq.*; Md. Code Ann., Health Gen. §§ 2-601 *et seq.*; Mass. Gen. Laws ch. 12, §§ 5A *et seq.*;

Mich. Comp. Laws §§ 400.601 *et seq.*; Minn. Stat. §§ 15C.01 *et seq.*; Mont. Code Ann. §§ 17-8-401 *et seq.*; Nev. Rev. Stat. §§ 357.010 *et seq.*; N.J. Stat. Ann. §§ 2A:32C-1 *et seq.*; N.M. Stat. Ann. §§ 27-14-1 *et seq.*; N.Y. State Fin. Law Art. XIII §§ 187 *et seq.*; N.C. Gen. Stat. §§ 1-605 *et seq.*; Okla. Stat. tit. 63, §§ 5053 *et seq.*; R.I. Gen. Laws §§ 9-1.1-1 *et seq.*; Tenn. Code Ann. §§ 71-5-181 *et seq.*; Tex. Hum. Res. Code Ann. §§ 36.001 *et seq.*; Tex. Hum. Res. Code. Ann. §§ 32.039 *et seq.*; Va. Code Ann. §§ 8.01-216.1 *et seq.*; Vt. Stat. Ann. tit. 32, §§ 630 *et seq.*; Wash Rev. Code §§ 74.66.005 *et seq.*; 2018 P.R. Act 154 (H.B. 1627); Chicago Mun. Code §§ 1-21-010 *et seq.*; Hallandale Beach Code of Ordinances §§ 8-201 *et seq.*; Broward Cnty. Code of Ordinances §§ 1-276 *et seq.*; Miami-Dade Cty. Code §§ 21-255 *et seq.*; Cal. Ins. Code § 1871.7; and 740 Ill. Comp. Stat. §§ 92/1 *et seq.*;

B. That judgment be entered against Defendants in the amount of each false or fraudulent claim, multiplied as provided for in 31 U.S.C. § 3729(a), plus a civil penalty of not less than eleven thousand four hundred sixty-three dollars ($11,463) or more than twenty-two thousand nine hundred twenty-seven dollars ($22,927) per false claim, as provided by 31 U.S.C. § 3729(a) and 15 C.F.R. § 63(a)(3),[141] to the extent such multiplied penalties shall fairly compensate the United States of America for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

C. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of California or its political subdivisions multiplied as provided for in Cal. Gov't Code § 12651(a), plus a civil penalty of not less than eleven thousand four hundred sixty-three dollars ($11,463) or more than twenty-two thousand nine hundred twenty-

[141] These figures are subject to change pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, Pub. L. 101-410, 104 Stat. 890 (Oct. 5, 1990), as amended.

seven dollars ($22,927) per false claim, as provided by Cal. Gov't Code § 12651(a),[142] to the extent such penalties shall fairly compensate the State of California or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

D. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of Colorado or its political subdivisions multiplied as provided for in Colo. Rev. Stat. § 25.5-4-305(1), plus a civil penalty of not less than the minimum civil penalty and not more than the maximum civil penalty allowed under the federal False Claims Act (31 U.S.C. § 3729(a)(1)) per false claim, as provided by Colo. Rev. Stat. § 25.5-4-305(1), to the extent such multiplied penalties shall fairly compensate the State of Colorado or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

E. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of Connecticut multiplied as provided for in Conn. Gen. Stat. § 4-275(b)(2), plus a civil penalty of not less than eleven thousand four hundred sixty-three dollars ($11,463) or more than twenty-two thousand nine hundred twenty-seven dollars ($22,927) per false claim, as provided by Conn. Gen. Stat. § 4-275(b)(1),[143] to the extent such multiplied penalties shall fairly compensate the State of Connecticut for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

[142] These figures are subject to change pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, Pub. L. 101-410, 104 Stat. 890 (Oct. 5, 1990), as amended.
[143] These figures are subject to change pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, Pub. L. 101-410, 104 Stat. 890 (Oct. 5, 1990), as amended.

F. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of Delaware multiplied as provided for in Del. Code Ann. tit. 6, §1201(a), plus a civil penalty of not less than five thousand five hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) per false claim, as provided by Del. Code Ann. tit. 6, §1201(a), to the extent such multiplied penalties shall fairly compensate the State of Delaware for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

G. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the District of Columbia, multiplied as provided for in D.C. Code § 2-381.02(a), plus a civil penalty of not less than five thousand five hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) per false claim, and the costs of this civil action brought to recover such penalty and damages, as provided by D.C. Code § 2-381.02(a), to the extent such multiplied penalties shall fairly compensate the District of Columbia for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

H. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of Florida or its agencies multiplied as provided for in Fla. Stat. § 68.082(2), plus a civil penalty of not less than five thousand five hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) per false claim, as provided by Fla. Stat. Ann. § 68.082(2), to the extent such multiplied penalties shall fairly compensate the State of Florida or its agencies for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

I. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of Georgia or its political subdivisions multiplied as provided for in Ga. Code Ann. § 49-4-168.1(a), plus a civil penalty of not less than five thousand five hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) per false claim, as provided by Ga. Code Ann. § 49-4-168.1(a), to the extent such multiplied penalties shall fairly compensate the State of Georgia or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

J. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of Hawaii, multiplied as provided for in Haw. Rev. Stat. § 661-21(a), plus a civil penalty of not less than five thousand five hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) per false claim, as provided by Haw. Rev. Stat. § 661-21(a), to the extent such multiplied penalties shall fairly compensate the State of Hawaii for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

K. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of Illinois, multiplied as provided for in 740 Ill. Comp. Stat. § 175/3(a)(1)(A), plus a civil penalty of not less than five thousand five hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) per false claim, as provided by 740 Ill. Comp. Stat. § 175/3(a)(1)(A), and the costs of this civil action as provided by 740 Ill. Comp. Stat. § 175/3(a)(1)(B), to the extent such penalties shall fairly compensate the State of Illinois for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

L. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of Indiana, multiplied as provided for in Ind. Code § 5-11-5.5-2(b), plus a civil penalty of at least five thousand dollars ($5,000) per false claim, as provided by Ind. Code § 5-11-5.5-2(b), to the extent such penalties shall fairly compensate the State of Indiana for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

M. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of Iowa, multiplied as provided for in Iowa Code § 685.2(1), plus a civil penalty of not less than eleven thousand four hundred sixty-three dollars ($11,463) or more than twenty-two thousand nine hundred twenty-seven dollars ($22,927) per false claim,[144] as provided by Iowa Code § 685.2(1), to the extent such multiplied penalties shall fairly compensate the State of Iowa or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

N. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by Louisiana's medical assistance programs, multiplied as provided for in La. Rev. Stat. Ann. § 46:438.6(B)(2), plus a civil penalty of no less than five thousand five hundred dollars ($5,500) and no more than eleven thousand dollars ($11,000) per false claim, plus payment of interest as provided for in La. Rev. Stat. Ann. § 46:438.6(C)(1)(b), to the extent such multiplied fines and penalties shall fairly compensate the State of Louisiana's

[144] These figures are subject to change pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, Pub. L. 101-410, 104 Stat. 890 (Oct. 5, 1990), as amended.

medical assistance programs for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

O. That judgment be entered in Relator's favor and against Defendants for restitution to the State of Maryland or its political subdivisions for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in Md. Code Ann., Health-Gen. § 2-602(a), multiplied as provided for in Md. Code Ann., Health-Gen. § 2-602(b)(1)(ii), plus a civil penalty of not more than ten thousand dollars ($10,000) per false claim, pursuant to Md. Code Ann., Health-Gen. § 2-602(b)(1)(i), to the extent such penalties fairly compensate the State of Maryland or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

P. That judgment be entered in Relator's favor and against Defendants for restitution to the Commonwealth of Massachusetts or its political subdivisions in the amount of a civil penalty of not less than eleven thousand four hundred sixty-three dollars ($11,463) or more than twenty-two thousand nine hundred twenty-seven dollars ($22,927) per false claim, plus three times the amount of damages, including consequential damages, sustained by Massachusetts as the result of Defendants' actions, plus the expenses of the civil action brought to recover such penalties and damages, as provided by Mass. Gen. Laws ch. 12. § 5B,[145] to the extent such penalties shall fairly compensate the Commonwealth of Massachusetts or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

[145] These figures are subject to change pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, Pub. L. 101-410, 104 Stat. 890 (Oct. 5, 1990), as amended.

Q. That judgment be entered in Relator's favor and against Defendants for restitution to the State of Michigan or its political subdivisions for the value of payments or benefits provided as a result of Defendants' unlawful acts, plus a civil penalty of triple the amount of damages suffered by Michigan as a result of Defendants' unlawful conduct, as well as not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) per false claim, as provided by Mich. Comp. Laws § 400.612(1), as well as the costs incurred by both Michigan and Relator, as provided by §§ 400.610a(9) and 400.610b, in order to fairly compensate the State of Michigan or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

R. That judgment be entered in Relator's favor and against Defendants for restitution to the State of Minnesota or its political subdivisions for the value of payments or benefits provided as a result of Defendants' unlawful acts, plus a civil penalty of triple the amount of damages suffered by Minnesota as a result of Defendants' unlawful conduct, as well as not less than five thousand five hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) per false claim, as provided by Minn. Stat. § 15C.02(a), as well as the costs incurred by both Michigan and Relator, as provided by Minn. Stat. § 15C.12, in order to fairly compensate Minnesota or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

S. That judgment be entered in Relator's favor and against Defendants for restitution to the State of Montana or its political subdivisions for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in Mont. Code Ann. § 17-8-403, multiplied as provided for in Mont. Code Ann. § 17-8-403(2), plus a civil

penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) per false claim, pursuant to Mont. Code Ann. § 17-8-403(2), to the extent such multiplied penalties shall fairly compensate the State of Montana or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

T. That judgment be entered in Relator's favor and against Defendants for restitution to the State of Nevada for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in Nev. Rev. Stat. § 357.040, multiplied as provided for in Nev. Rev. Stat. § 357.040(1), plus a civil penalty of not less than eleven thousand four hundred sixty-three dollars ($11,463) or more than twenty-two thousand nine hundred twenty-seven dollars ($22,927) per false claim, pursuant to Nev. Rev. Stat. § 357.040(2)(c),[146] to the extent such multiplied penalties shall fairly compensate the State of Nevada for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

U. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of New Jersey or its political subdivisions multiplied as provided for in N.J. Stat. Ann. § 2A:32C-3, plus a civil penalty of not less than the minimum civil penalty and not more than the maximum civil penalty allowed under the federal False Claims Act (31 U.S.C. § 3729(a)(1)) per false claim, to the extent such multiplied penalties shall fairly compensate the State of New Jersey or its political subdivisions for losses resulting from the

[146] These figures are subject to change pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, Pub. L. 101-410, 104 Stat. 890 (Oct. 5, 1990), as amended.

various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

V. That judgment be entered in Relator's favor and against Defendants for restitution to the State of New Mexico or its political subdivisions for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in N.M. Stat. Ann. § 27-14-4 and N.M. Stat. Ann. § 44-9-3(C), multiplied as provided for in N.M. Stat. Ann. § 27-14-4 and N.M. Stat. Ann. § 44-9-3(C)(1), plus a civil penalty of not less than five thousand dollars ($5,000) and not more than ten thousand dollars ($10,000) per false claim, as provided by N.M. Stat. Ann. § 44-9-3(C)(2), to the extent such multiplied penalties shall fairly compensate the State of New Mexico or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery, as well as the costs of this action and reasonable attorney fees as provided by N.M. Stat. Ann. § 44-9-3(C)(3)-(4);

W. That judgment be entered in Relator's favor and against Defendants for restitution to the State of New York or its political subdivisions for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in N.Y. State Fin. Law § 189(1), multiplied as provided for in N.Y. State Fin. Law § 189(1), plus a civil penalty of not less than six thousand dollars ($6,000) or more than twelve thousand dollars ($12,000) per false claim, pursuant to N.Y. State Fin. Law § 189(1), to the extent such multiplied penalties shall fairly compensate the State of New York or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

X. That judgment be entered in Relator's favor and against Defendants for restitution to the State of North Carolina for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in N.C. Gen. Stat. § 1-607, multiplied as provided for in N.C. Gen. Stat. § 1-607(a), plus a civil penalty of not less than five thousand five hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) per false claim, as provided by N.C. Gen. Stat. § 1-607(a), to the extent such multiplied penalties shall fairly compensate the State of North Carolina for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

Y. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of Oklahoma or its political subdivisions multiplied as provided for in Okla. Stat. tit. 63, § 5053.1(B), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) per false claim, as provided by Okla. Stat. tit. 63, § 5053.1(B), to the extent such multiplied penalties shall fairly compensate the State of Oklahoma or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

Z. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of Rhode Island or its political subdivisions multiplied as provided for in R.I. Gen. Laws § 9-1.1-3(a), plus a civil penalty of not less than five thousand five hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) per false claim, as provided by R.I. Gen. Laws § 9-1,1-3(a), to the extent such multiplied penalties shall fairly compensate the State of Rhode Island or its political subdivisions for losses resulting from

the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

AA. That judgment be entered in Relator's favor and against Defendants for restitution to the State of Tennessee for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in Tenn. Code Ann. § 71-5-182, multiplied as provided for in Tenn. Code Ann. § 71-5-182(a)(l), plus a civil penalty of not less than five thousand dollars ($5,000) or more than twenty-five thousand dollars ($25,000) per false claim, pursuant to Tenn. Code Ann. § 71-5-182(a)(l),[147] to the extent such multiplied penalties shall fairly compensate the State of Tennessee for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

BB. That judgment be entered in Relator's favor and against Defendants for restitution to the State of Texas for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in Tex. Hum. Res. Code Ann. § 36.052(a) and Tex. Hum. Res. Code Ann. § 32.039, multiplied as provided for in Tex. Hum. Res. Code Ann. § 36.052(a)(4), the interest on the value of such payments or benefits at the prejudgment interest rate in effect on the day the payment or benefit was paid or received, for the period from the date the payment or benefit was paid or received to the date that restitution is made to the State of Texas, pursuant to Tex. Hum. Res. Code Ann. § 36.052(a)(2), plus an administrative penalty not to exceed twice the amount paid, as provided by Tex. Hum. Res. Code. Ann. § 32.039(c)(2), plus a civil penalty of not less than the minimum civil penalty and not more than the maximum

[147] These figures are subject to change pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, Pub. L. 101-410, 104 Stat. 890 (Oct. 5, 1990), as amended.

civil penalty allowed under the federal False Claims Act (31 U.S.C. § 3729(a)(1)) per false claim, as provided by Tex. Hum. Res. Code Ann. § 36.052(a)(3)(A) & (B), plus an administrative penalty of not less than five thousand dollars ($5,000) or more than fifteen thousand dollars ($15,000) for each unlawful act, pursuant to Tex. Hum. Res. Code. Ann. § 32.039(c)(2)(A) & (B), to the extent such multiplied penalties shall fairly compensate the State of Texas for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

CC. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of Vermont or its political subdivisions, multiplied as provided for in Vt. Stat. Ann. tit. 32, § 631(b)(2), plus a civil penalty of not less than five thousand five hundred dollars ($5,500) and not more than eleven thousand dollars ($11,000) per false claim, as provided by Vt. Stat. Ann. tit. 32, § 631(b)(1), as well as the costs incurred by the State of Vermont, as provided by Vt. Stat. Ann. tit. 32, § 631(b)(3), in order to fairly compensate the State of Vermont or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

DD. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the Commonwealth of Virginia, multiplied as provided for in Va. Code Ann. § 8.01-216.3(A), plus a civil penalty of not less than five thousand five hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) per false claim, as provided by Va. Code Ann. § 8.01-216.3(A), to the extent such multiplied penalties shall fairly compensate the Commonwealth of Virginia for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

EE. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of Washington or its political subdivisions multiplied as provided for in Wash. Rev. Code § 74.66.020 (1), plus a civil penalty of not less than eleven thousand four hundred sixty-three dollars ($11,463) or more than twenty-two thousand nine hundred twenty-seven dollars ($22,927) per false claim, as provided by Wash. Rev. Code § 74.66.020(1) and Wash. Admin. Code § 44-02-010,[148] to the extent such penalties shall fairly compensate the State of Washington or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

FF. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the Commonwealth of Puerto Rico and its political subdivisions, multiplied as provided for in 2018 P.R. Act 154 (H.B. 1627), § 4.01(1)(d), plus a civil penalty of not less than eleven thousand four hundred sixty-three dollars ($11,463) or more than twenty-two thousand nine hundred twenty-seven dollars ($22,927) per false claim, as provided by 2018 P.R. Act 154 (H.B. 1627), § 4.01(1)(d),[149] as well as the costs incurred by Relator and the Commonwealth of Puerto Rico, as provided by 2018 P.R. Act 154 (H.B. 1627), § 4.01(3), in order to fairly compensate the Commonwealth of Puerto Rico or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

[148] These figures are subject to change pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, Pub. L. 101-410, 104 Stat. 890 (Oct. 5, 1990), as amended.
[149] These figures are subject to change pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, Pub. L. 101-410, 104 Stat. 890 (Oct. 5, 1990), as amended.

GG. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the City of Chicago, multiplied as provided for in Chicago Mun. Code § 1-22-020, plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) per false claim, as provided by Chicago Mun. Code § 1-22-020, as well as the costs incurred by Relator and the City of Chicago, as provided by Chicago Mun. Code § 1-22-020, in order to fairly compensate the City of Chicago for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

HH. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the City of Hallandale Beach, multiplied as provided for in Hallandale Beach Code of Ordinances § 8-204(c)(1), plus civil penalties, as provided by Hallandale Beach Code of Ordinances § 8-204(c)(5), as well as the costs incurred by Relator and the City of Hallandale Beach, as provided by Hallandale Beach Code of Ordinances § 8-207(a), in order to fairly compensate the City of Hallandale Beach for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

II. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by Broward County, multiplied as provided for in Broward Cty. Code of Ordinances § 1-279(c)(1), as well as the costs incurred by Relator and Broward County, as provided by Broward Cty. Code of Ordinances § 1-283(a)-(b), in order to fairly compensate Broward County for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

JJ. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by Miami-Dade County, multiplied as provided for in Miami-Dade Cty. Code § 21-258(3)(a), as well as the costs incurred by Relator and Broward County, as provided by Miami-Dade Cty. Code §§ 21-258(3)(c), -262(1)-(2), in order to fairly compensate Miami-Dade County for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

KK. That judgment be entered in Relator's favor and against Defendants in the amount of each false claim for compensation that Defendants presented or caused to be presented to a California insurance company, multiplied as provided for in Cal. Ins. Code § 1871.7(b), plus a civil penalty of not less than five thousand dollars ($5,000) and not more than ten thousand dollars ($10,000) per false claim, as provided for in Cal. Ins. Code § 1871.7(b), as well as the reasonable attorney's fees and costs incurred by Relator and the California Department of Insurance, as provided for in Cal. Ins. Code § 1871.7(g)(1)(A)(ii)-(iii);

LL. That the Court, pursuant to Cal. Ins. Code § 1871.7(b) and 740 Ill. Comp. Stat. § 92/5(b), issue an order preventing the Defendants from transferring, concealing, or dissipating the proceeds of its illegal conduct;

MM. That judgment be entered in Relator's favor and against Defendants in the amount of each false claim for compensation that Defendants presented or caused to be presented to an Illinois insurance company, multiplied as provided for in 740 Ill. Comp. Stat. § 92/5(b), plus a civil penalty of not less than five thousand dollars ($5,000) and not more than ten thousand dollars ($10,000) per false claim, as provided for in 740 Ill. Comp. Stat. § 92/5(b), as well as the reasonable attorney's fees and costs incurred by Relator, as provided for in 740 Ill. Comp. Stat. § 92/25(e);

NN. That Defendants be ordered to disgorge all sums by which they have been enriched unjustly by their wrongful conduct;

OO. That judgment be granted for Relator against Defendants for all costs, including, but not limited to, court costs, expert fees and all attorneys' fees incurred by Relator in the prosecution of this suit;

PP. That the Court issue an order enjoining the Defendants from continuing to engage in the fraudulent conduct alleged herein; and

QQ. That this Court award such further relief as it deems just and proper.

XIV. JURY DEMAND

Plaintiff hereby demands a trial by jury on all claims so triable in this action.

Dated: March 3, 2020

By: _____
Michael D. Fitzgerald

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